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In the Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL,
PETITIONER

v.

LEROY CARHART, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

(VOLUME 2)

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preferable procedure at the same gestational age than a D & E, if you are able to have less need for instrumentation inside the uterus." (Tr. 1425, Test. Dr. Cook.)

If a physician is attempting to abort a 17-week fetus via D & E and the fetus delivers in one pass, except for the fetal head which becomes stuck in the internal cervical os, Dr. Cook believes it would be medically reasonable to administer nitroglycerin[83] in an attempt to loosen the cervix and "do what [he] can to manipulate the head out of the cervix which could include a single small incision on the cervix." If this procedure did not work, the physician could perform a crushing or aspiration procedure on the fetal head without violating the Act because the fetus would no longer be alive because "it's now been hanging out for some number of minutes with complete occlusion of the cord. . . . You can't completely occlude a cord for more than a few minutes and still have a live fetus." (Tr. 1462-65, Test. Dr. Cook; *see also* Tr. 1598-1602, Test. Dr. Shadigian (in same situation, physician could try to change angle of baby's head, use maneuvers similar to those used in breech deliveries, administer medicine to increase uterine contractions, and apply nitroglycerin to relax the cervix).)

In the above scenario, if the woman was bleeding such that a quick delivery was necessary, Dr. Shadigian stated that the physician could use forceps to grasp a part of the baby, "pull harder" to cause dismember-

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[83] Dr. Lockwood testified that nitroglycerin—which directly relaxes smooth muscle tissue—is used in obstetrics to effect rapid uterine relaxation. The uterus is made of smooth muscle tissue. Because the cervix is comprised of only 30 to 40% smooth muscle tissue, with some exceptions, *in utero* nitroglycerin is generally not effective for dilating the cervix. (Tr. 1760, Test. Dr. Lockwood.)

ment, and try to change the angle of the fetus to pull it out. If the mother is "hemorrhaging and you need to get the baby out, [it] could be possible to collapse the skull" without violating the standard of care. (Tr. 1601, Test. Dr. Shadigian.)

Dr. Cook criticized as "extreme and absurd" the examples given in Dr. Philip Darney's March 12, 2003, letter to Senator Feinstein[84] of cases in which the intact D & E procedure was purportedly critical to the safety of Dr. Darney's surgery.

> When they first presented this to me, I honestly thought it was laughable and didn't believe these were real cases because I could not imagine somebody managing these pregnancies in this way . . . . [I]n the first case . . . you have a placenta previa, meaning you have a placenta that is presenting ahead of the baby, and you're having so much bleeding that you're replacing blood products, and you have a patient who is coagularpathic . . . the last thing I know of any maternal fetal medicine person would do or obstetrician would be to attempt further vaginal procedures on that patient. That patient needs a definitive procedure like yesterday, so we would have proceeded with hysterotomy, removal of the placenta, removal of the fetus, and the reason for that is that you want to be able to correct the situation rapidly. Also, there is at least 5% risk of a placenta accreta which is the next situation . . . . [w]hich would be an even further complication where you require hysterectomy to

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[84] Dr. Darney's letter is reproduced in my summary of the congressional record in this case, *supra*.

control bleeding, so to me, it was a very poorly made decision . . . .

. . . .

[Y]ou could pretty much consult any basic obstetrics text, and they would say that having the situation of placenta previa would be a contraindication to vaginal delivery. . . . [T]hey had a patient who had this history of this placenta previa, and she was already known to have risk factors with a clotting disorder, and they went ahead, despite that, and tried to deliver her vaginally by intentionally causing contractions and cervical change which is why you have bleeding with the placenta previa . . . because the cervix starts to dilate or the lower end segment thins out, so they intentionally caused a situation that [they] knew was going to complicate bleeding in a patient with underlying risk factors . . . and then when they decided the heavy bleeding was so great they couldn't keep up, then they did this intact D & X procedure . . . . They would never have had to have gone down that road at all nor put that patient in jeopardy had they proceeded with what I think any reasonable maternal fetal medicine person would have done which was a hysterotomy.

(Tr. 1470-72 & 1476-77, Test. Dr. Cook; Ct.'s Ex. 3.)

Dr. Lockwood also addressed Dr. Darney's example of the 25-year-old with two previous vaginal deliveries, bleeding placenta previa, and a clotting disorder at 20 weeks who was referred for termination of pregnancy. Noting the lack of information regarding the patient's blood condition, Dr. Lockwood stated that if the physician had to "move very quickly in doing the termi-

nation" because of a bleeding situation, "the time to do a D & E and D & X, at least according to Chasen's study, was the same." Dr. Lockwood opined that "if the law were in force, they could have injected KCI. They are very skilled at doing that at UCSF. They could have injected lidocaine. They could have injected Digoxin. A variety of ways to induce fetal death, then have done an intact D & X." (Tr. 1690-92, Test. Dr. Lockwood.)

Dr. Lockwood expressed "shock" about Dr. Darney's example of a 38-year-old patient with three previous cesarean deliveries, evidence of placenta accreta, and a 75% risk of massive hemorrhage and hysterectomy at the time of delivery who was referred for pregnancy termination at 23 weeks.

> The placenta accreta is where the placenta invades the wall of the uterus. I see many of these patients in New York . . . . [T]hese patients . . . generally are not symptomatic to 36 weeks. I have no idea why they would want to do a termination at 22 weeks, unless the woman was interested in a termination. The management of placenta accreta is cesarean hysterectomy. Anyone that attempts to do anything short of that is playing an incredible game with this patient's life. Now, this may have been a patient that deeply wanted to retain her fertility. Well, in which case, why was she terminating a pregnancy? That makes no sense to me. It's very clear from the literature . . . [and] from our experience that the critical event, in the management of placenta accreta, is definitive surgery at the time. Conservative management has failed time and time again. It's placed the patient's life in great jeopardy. The only conceivable reason you might

> do it is in a woman who['s] never had children, desperately desires children. If the accreta were small, I have no idea why anyone would try to do this, to be honest with you. So should they have done this? No. Did they get incredibly lucky? Yes. If there had been a bad event, would they have been sued by many, many lawyers? Yes, absolutely.

(Tr. 1693-94, Test. Dr. Lockwood.)

Dr. Shadigian finds no basis on which to conclude that the intact D & E procedure is safer than other methods of abortion because her international and domestic literature search revealed no studies stating "what the correct indication should be for a D & X. We don't know what the short-term complications are. We don't know the long-term complications. And because it hasn't been studied at all, we can't really even compare it to a D & E or to a medical induction of labor." (Tr. 1522-23, Test. Dr. Shadigian.)

> [This lack of formal study of the intact D & E procedure] tells me, I don't know if it's safe or not. I don't know if it's going to cause women even more problems in the end or less problems. And when something is so unstudied . . . I'm just not willing to . . . put my patients' own reproductive health on the line for something [when] I know we already have good data on D & E procedures and medical induction procedures.

(Tr. 1523, Test. Dr. Shadigian.) "[M]edicine is based on evidence. It's based on doing studies. It's based on compar[ing] what we know to what we don't know. And in the absence of that, [practitioners' assertions that the intact D & E is safe] are just anecdotal

thoughts or feelings that a physician may have." (Tr. 1524, Test. Dr. Shadigian.)

According to Dr. Shadigian, while the intact D & E procedure involves less instrument passes than the traditional D & E, which "should" reduce the risk of laceration and perforation, the "whole picture as to the safety of the procedure" also includes short-term and long-term complications, which are impossible to gauge if women do not return to their abortion provider for follow-up care. (Tr. 1526-27, Test. Dr. Shadigian (citing the 1999 "Picker study" which showed that only 29% of women follow up with their abortion provider).)

While the risks of the intact D & E procedure have not been established in medical and scientific literature, Dr. Lockwood believes that the "risks of D & E and D & X could be comparable." However, beyond the "intuitive or theoretical advantages" of performing an intact D & E, Dr. Lockwood does not see any evidence that the intact D & E is a "safer procedure." (Tr. 1712, Test. Dr. Lockwood.)

The intact D & E procedure "might be reasonable in some circumstances," but Dr. Lockwood cannot "envision a circumstance in which the D & X procedure would be required as opposed to a D & E or a medical induction." In Dr. Lockwood's opinion, the short-term risks of the intact D & E procedure would be identical to those of a D & E. "[T]he theoretical benefit of an intact D & X is fewer manipulations, which might reduce the risks of perforation. Risk of perforation is not insubstantial . . . . [I]t's the most feared complication. So that, I think, is the great appeal of the procedure . . . . [and] a theoretical advantage." Although reports from Europe are "conflicting" regarding the relationship between abortion and subsequent

preterm birth, the "primary" and "most serious" "long-term concern" with the intact D & E procedure is subsequent preterm birth.

> [W]e don't know what the risk would be. Some have argued that the further along you go, the greater the risk because the laminaria are not the most physiologic way to dilate the cervix. Others have argued that earlier D & Es might even be more dangerous, because you're mechanically dilating the cervix. I think, since this is, in fact in the focus of my professional existence, it's a topic I'm very, very interested in. And I am concerned, in general, about the association of abortions and prematurity. And I don't know the answer, to be honest with you. But I'm certainly suspicious and would certainly like more data.

(Tr. 1712-15, Test. Dr. Lockwood.)

v. INDUCTION

Dr. Frederiksen testified that in the early portion of the second trimester, before 15 to 16 weeks, labor induction is less successful and difficult to perform. (Ex. 123, Test. Dr. Frederiksen 1171.) Dr. Shadigian told the court that medical-induction pregnancy terminations after 18 or 20 weeks are "safe and effective" procedures. (Tr. 1534, Test. Dr. Shadigian.) At about 20 weeks, several physicians testified that induction and D & E terminations are comparable for safety purposes. (Tr. 1555-56, Test. Dr. Shadigian ("the medical induction and D & E are safe procedures, especially in the 16- to 20-week range"); Tr. 1765, Test. Dr. Lockwood (after 20 weeks, the rates of safety of D & E and induction are "comparable"; safety rate of intact D & E not yet known); Ex. 123, Test. Dr.

Frederiksen 1174 (between 20 and 24 weeks of gestation, the risks of D & E and medical induction may be similar).) Dr. Creinin knows of no medical data supporting the claim that induction is safer than a D & E for aborting a fetus after 18 or 20 weeks of gestation. (Ex. 122, Test. Dr. Creinin 721-22.)

Although induction abortion is a safe method, based on his experience, CDC statistics, and published medical literature, Dr. Chasen believes the D & E is the safest (and most common) method of abortion after 20 weeks of gestation. (Ex. 121, Test. Dr. Chasen 1578 & 1682-83; Ex. 124, Test. Dr. Hammond 541-43 (D & E safer and more common after 20 weeks of gestation).) Based on her experience and medical literature, Dr. Frederiksen believes labor induction is safe, but the intact D & E is the safest method of performing a second-trimester abortion. The D & E has evolved and become safer over time. (Ex. 123, Test. Dr. Frederiksen 1051 & 1066.)

Dr. Broekhuizen believes that D & E and labor induction are both safe abortion procedures and that the complications of cervical and uterine damage, hemorrhage, and infection are common to both medical-induction and D & E abortion. However, he also believes that, as compared with the D & E procedure, labor induction poses less risk of injury by instrumentation and less risk of trauma. (Ex. 120, Test. Dr. Broekhuizen 504 & 579-80.) Dr. Frederiksen testified that labor-induction abortion poses a lower risk of uterine perforation than the D & E method. (Ex. 123, Test. Dr. Frederiksen 1213.)

Dr. Clark believes that labor induction is a safe and recognized abortion procedure. (Ex. 891, Test. Dr. Clark 2306.) However, barring medical complications,

he views the D & E as the preferable second-trimester abortion option before 18 weeks of gestation. It is the procedure Dr. Clark would recommend to his patients at that gestational age because labor induction is much more difficult for the mother prior to 18 weeks of gestation; is uncomfortable until the mother is given an epidural; and can be psychologically draining on the mother. Moreover, a D & E takes less than an hour, while labor induction can take up to 48 hours. (Ex. 891, Test. Dr. Clark 2405-07.)

According to Dr. Cook, since D & Es are performed at an earlier gestational age, it is more accurate to compare the intact D & E, which is performed later in pregnancy, to contemporary induction techniques using prostaglandins administered orally, vaginally, or intramuscularly. (Tr. 1355 & 1367-68, Test. Dr. Cook.) Despite the lack of randomized controlled trials comparing contemporary induction techniques to the D & E, Dr. Cook believes that modern induction procedures are safer than the D & E after 20 weeks of gestation. (Tr. 1423, Test. Dr. Cook.) After 20 weeks, the D & E becomes more complicated due to "[a] larger, more distended uterus, a larger fetus, greater calcification of the fetus. More difficulty disarticulating the fetus . . . . more cervical dilation than is necessary." (Tr. 1424, Test. Dr. Cook.)

Dr. Sprang's experience and review of medical literature and textbooks lead him to the opinion that the "safety of induction as a termination method . . . [is] at least, comparable to D & E after 20 weeks." (Tr. 1129, Test. Dr. Sprang.) In his expert report, Dr. Sprang concluded that "induction is, in general, the safest method of abortion for the pregnant woman beyond approximately 20 to 22 weeks given the

chemical agents used for induction to prepare the cervix and the uterus for delivery and that induction, unlike other methods, does not necessarily involve introduction of instruments into the uterus." (Tr. 1207, Test. Dr. Sprang.) Dr. Sprang's preference is to use induction because he "like[s] natural things," induction is a "more natural process," and "it's just more physiologic. You're basically doing what the body was going to do anyway." (Tr. 1132 & 1200, Test. Dr. Sprang.) Because Dr. Sprang believes that induction is the safest abortion option at 20 weeks of gestation, he "probably wouldn't even bring . . . up" the D & E option to his patients because "in my belief, induction is [a] safer process for the patient at 20 weeks." (Tr. 1213-14, Test. Dr. Sprang.)

Dr. Hammond believes that labor induction is a very safe second-trimester abortion method, and that from 20 to 24 weeks, D & E and labor induction are about equal in terms of safety. (Ex. 124, Test. Dr. Hammond 541-42.)

According to Dr. Lockwood, after 21 weeks, most women and physicians choose surgical abortions over induction abortions. (Tr. 1749-50, Test. Dr. Lockwood.) However, Dr. Broekhuizen testified that the majority of patients who want an intact fetus choose labor induction. (Ex. 120, Test. Dr. Broekhuizen 580.)

Dr. Cook believes that for many maternal-complication cases, as with women having major cardiovascular or central nervous system conditions, monitored medical induction is more appropriate to terminate pregnancies after 16 weeks than the "less physiologic, more invasive and potentially more complicated" surgical options available so that sophisticated monitoring can be used to demonstrate that the patient is

"doing well during the process." (Tr. 1279, Test. Dr. Cook.)

For fetal anomalies after 20 weeks of gestation, Dr. Shadigian would "generally" recommend medical induction because:

> [T]he safety data is so much better on medical inductions, especially with the newer Prostaglandins. It used to take much longer to induce labors and it was more distasteful for women and even more difficult to manage people over three days. But now, we have Misoprostol and we can actually deliver babies within four to 24 hours with the new medication, so it's safer. And, also, the older studies show that there is a lot less maternal mortality for medical inductions for 21 weeks and later.

(Tr. 1520, Test. Dr. Shadigian.) However, Dr. Westhoff explained that induction may be contraindicated when fetal anomalies exist, including fetal anomalies that involve the presence of large body parts, such as hydrocephalus. Labor induction will not likely be successful in these circumstances, and a D & E will ultimately be required. (Ex. 126, Test. Dr. Westhoff 821-22.)

Although Dr. Fitzhugh believes that second-trimester D & Es and induction abortions are both "relatively safe," inductions involve a "much higher" discomfort level for the patient, "much greater" hospitalization time, and a "much greater" amount of care. (Tr. 259-60, Test. Dr. Fitzhugh; *see also* Ex. 121, Test. Dr. Chasen 1580 & 1588 (medical induction requires hospitalization for several hours or days, but the D & E is an outpatient procedure allowing the woman to go

home or to work during the process; with medical induction, the woman receives an epidural with no sedation; in contrast, Dr. Chasen performs D & Es with general anesthesia or local anesthesia and substantial degrees of sedation); Ex. 123, Test. Dr. Frederiksen 1067-68 (labor induction riskier than D & E because second-trimester uterus is not ready for labor and cervix is not ready to dilate; process of inducing uterine contraction and causing the cervix to change from long and closed to short and dilated can take from 9 to 48 hours; medical induction abortion is labor and delivery-a painful process); Ex. 125, Test. Dr. Paul 91-92 (labor induction can be difficult and women tend to prefer shorter D & E procedure); Ex. 126, Test. Dr. Westhoff 812-13 (uterine contractions of induced labor abortion similar to contractions women experience during childbirth where labor is induced using similar medications; induced labor contractions more painful than spontaneous labor contractions).)

Dr. Lockwood identified the primary risks of medical-induction abortions between 20 and 24 weeks as retained placenta,[85] infection, and rarely, tearing of the cervix. (Tr. 1708-09, Test. Dr. Lockwood; *see also* Ex. 123, Test. Dr. Frederiksen 1148 & 1078-81 (blood loss is possible complication of induction abortion; generally more blood is lost during induction abortion

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[85] Dr. Lockwood testified that retained placenta means the fetus delivers, but the placenta does not. Physicians typically wait a period of time for the placenta to deliver on its own. If it fails to do so, the placenta can be removed by suction curettage or manually with risks equivalent to a 10- to 12-week suction curettage procedure. Retained placenta in medical inductions may be viewed either as a side effect since it occurs 20% of the time, or as a complication. (Tr. 1710-11, Test. Dr. Lockwood.)

than with D & E; risk of infection exists with any second-trimester termination, but process of labor exposes uterus to vaginal organisms resulting in higher risk of infection with induction than with D & E; sepsis may arise during labor induction, necessitating a D & E to preserve life and health of mother).) According to Dr. Lockwood, the occurrence of these complications decreases with gestational age because "the uterus is . . . more biologically ready for labor as is the cervix. And it's already stretched out . . . and enlarged. And so those things . . . help contribute to the avoidance of lacerations or asymptomatic tears." (Tr. 1709, Test. Dr. Lockwood.)

Many of the physicians appearing before the court testified that one possible "complication" of induction procedures that does not occur with D & E procedures is retained placenta. In a normal induction procedure, the fetus passes first, the placenta follows shortly thereafter, the uterus contracts, and significant bleeding stops. If the fetus passes, but the placenta remains inside or is partially, but not completely, separated, the bleeding continues. If the bleeding becomes excessive and the placenta is not expelled, the patient must undergo immediate removal of the placenta by emergency operation. Emergency removal of the placenta does not occur in the D & E procedure because the fetus and placenta are removed at the same time during the procedure. (Tr. 142-43, Test. Dr. Doe; Ex. 123, Test. Dr. Frederiksen 1076-79 (separation of placenta can be long process associated with increased blood loss; retained placenta prevents uterus from fully contracting to stop bleeding; often necessary to surgically remove retained placenta in second-trimester induction procedures); Ex. 122, Test. Dr. Creinin 715-16 (labor

induction may not empty the uterus of fetal and placental tissue, necessitating follow-up surgery); Ex. 125, Test. Dr. Paul 86-87 (retained placenta is common complication of induction abortion; standard is to wait about two hours after delivery of fetus for delivery of placenta; if placenta not delivered, suction curettage is done, sometimes under general anesthesia, to remove placenta; if placenta is retained more than two hours after fetus is delivered, literature reflects increased risk of bleeding and fever).)

Dr. Knorr believes D & Es are safer than induction abortions. Placentas "come out complete" in induction abortions only 80% of the time because immature placentas are more firmly attached than more mature placentas and because the cord, which is gently pulled to deliver the placenta, tends to break. "While you're waiting for that placenta to come out over that half hour, generally that woman is bleeding, and there have been several times where I have been involved in that kind of procedure and have had to take the woman to the [operating room] hemorrhaging to remove that placenta and stop the blood flow." (Tr. 520-21, Test. Dr. Knorr; *see also* Tr. 975-76, Test. Dr. Bowes (overall, D & E is safer than induction; contraindications exist for inductions in the second trimester; retained placenta is complication of induction abortion); Tr. 1749, Test. Dr. Lockwood (there is 10 to 30% chance of retained placenta in medical-induction abortions; considers retained placenta to be a complication of induction method); Tr. 1137-39 & 1210-12, Test. Dr. Sprang (retained placenta not "complication" of induction; rather, it is "just a part of the process" in 10 to 20% of induction patients; "Everything we do," including inductions, creates standard risks of "hemorrhage, infection and

trauma to the tissue"; it is "a known part of medical abortions [inductions] that 5 to 10% of the time, the placenta won't follow immediately afterwards" and the patient will require D & C to remove retained products of conception); Ex. 121, Test. Dr. Chasen 1587 & 1608 (retained placenta and infection are common complications of medical induction that increase the risk of hemorrhage).)

Dr. Hammond stated that depending on the inducing agent used, in 15 to 30% of labor-induction cases, the placenta is retained and follow-up surgery is required. While waiting is an option, at some point the doctor must intervene to avoid the risk of infection and bleeding. The standard practice is to wait no more than two hours. Based on medical studies, waiting beyond two hours doubles the risk of hemorrhage, infection, and other major complications. Another more recent (late 1980s) study indicates the risk tends to rise after 30 minutes. Therefore, Dr. Hammond and his colleagues at Northwestern begin to consider surgical delivery of the placenta if it has not been delivered within 30 minutes after the fetus is delivered. The woman continues to be under epidural anesthesia at that time. (Ex. 124, Test. Dr. Hammond 580-86.)

Dr. Vibhakar believes induction abortions to be safe, but has experienced more cases of significant blood loss and infection with induction abortions than with D & E abortions. Several of Dr. Vibhakar's patients who had retained placenta after an induction have required emergency care to control hemorrhage. Dr. Vibhakar has seen a lower rate of retained placenta through use of misoprostol. (Tr. 321-23 & 392, Test. Dr. Vibhakar.) However, Dr. Creinin's research, and his discussions with the coauthor of his chapter on induction in an

obstetrics and gynecology textbook, have led him to conclude that the medications used today, including misoprostol, have not significantly improved the overall rate of complications related to induction abortions. (Ex. 122, Test. Dr. Creinin 717-18.)

Dr. Creinin noted other complications that are possible in induction-abortion procedures:

* Bleeding, perhaps enough to require a transfusion, may arise from abruption, infection, cervical injury, and uterine injury. (Ex. 122, Test. Dr. Creinin 715.)

* Labor induction requires administering high doses of medications, enough to override the body's internal mechanism for retaining the fetus and to cause the uterus to contract and expel the fetus at a time when it is not physiologically prepared to do so. The uterus can contract so strongly that "it can just break apart, to put it in simplistic terms." (Ex. 122, Test. Dr. Creinin 715.)

* There is a risk (albeit incredibly low) of disseminated intravascular coagulation arising from prolonged bleeding and the liver's inability to manufacture clotting factors as quickly as the body is consuming them. (Ex. 122, Test. Dr. Creinin 716-17.)

According to Drs. Chasen and Hammond, in women with medical complications who need a pregnancy terminated on an urgent basis, the intact or dismemberment D & E procedures are safer than induction because a woman who is already having medical problems is even more susceptible to the complications encountered with medical induction, medical induction

can take considerably longer than 24 hours, and its success is not as predictable. (Ex. 121, Test. Dr. Chasen 1610-11; Ex. 124, Test. Dr. Hammond 542-43 & 548 (labor-induction abortion, before 20 weeks in particular, is unpredictable in that it may take only six hours, but could take three days; the longer induction takes, the higher risk of complications such as infection and hemorrhage).)

Dr. Chasen explained that as the uterus contracts forcefully during an induction procedure, the placenta may be expressed or the membranes may rupture and the umbilical cord can get compressed or fall out of the cervix. These conditions deprive the fetus of oxygen, resulting in fetal asphyxiation that can last many minutes. (Ex. 121, Test. Dr. Chasen 1587-88.)

Several physician witnesses testified that in some cases, medical induction is unsuccessful despite prolonged labor. In such cases, a D & E may be required and if the D & E is not an available technique, the woman may need a hysterotomy. (Ex. 121, Test. Dr. Chasen 1587; Ex. 123, Test. Dr. Frederiksen 1077; *see also* Ex. 126, Test. Dr. Westhoff 823-24 (inductions can fail to expel fetus, requiring D & E to complete the abortion; in 10 to 25% of cases, induction fails to expel placenta and follow-up D & C is required); Ex. 891, Test. Dr. Clark 2409-10 (labor induction does not always succeed in emptying the uterus; as with D & E, instruments may need to be used to remove the placenta, and using instruments poses risk of infections and perforation of the uterus); Ex. 124, Test. Dr. Hammond 548-49 & 580 (inducing labor does not always work because some patients do not respond to medication or their response is so slow that the mother's health will be harmed unless pregnancy is promptly

terminated by D & E; failed induction less common when fetus has died; some patients arrive from outside areas where induction was attempted over period of days, and by the time Dr. Hammond sees them, they have infections and their underlying medical condition has worsened).)

Some physicians believe that induction abortions are "absolutely" contraindicated for patients who have placenta previa—a condition in which the placenta overlies the opening of the cervix, preventing the fetus from passing without causing heavy bleeding-or placenta accreta—a condition in which the placenta grows into the uterine wall and is difficult to separate without causing serious bleeding. (Tr. 26-28, Test. Dr. Doe; Ex. 120, Test. Dr. Broekhuizen 506 (in cases of placenta previa, after 24 weeks a cesarean section would be performed, and after 22 weeks, D & E causes less bleeding); Ex. 123, Test. Dr. Frederiksen 1081 (labor can cause profound maternal hemorrhage in women with placenta previa); Ex. 126, Test. Dr. Westhoff 818 (if cervix dilates in woman with placenta previa, maternal hemorrhage can occur); Ex. 891, Test. Dr. Clark 2350-54 (for patients with placenta previa, carrying pregnancy to term poses less risk than second-trimester abortion; if woman with placenta previa elects to abort second-trimester fetus, labor induction contraindicated due to risk of excessive bleeding, and dismemberment D & E is preferred second-trimester abortion method); Ex. 124, Test. Dr. Hammond 553-54 (labor induction absolutely contraindicated for women with complete placenta previa; if labor is induced, fetus would have to be delivered through the placenta, which cannot occur-and, even if it did, would result in severe maternal hemorrhage; in such circumstances, there are

only two logical options—hysterotomy or D & E, the latter of which is the better choice because at this stage of gestation, the uterus is a more vascular organ and cutting through it during a hysterotomy would result in severe bleeding and would make the uterus more prone to rupture in later pregnancies).)[86]

Others believe that induction abortions are contraindicated for women with chorioamnionitis who need evacuation of the uterus as soon as possible to control sepsis. (Tr. 326-27, Test. Dr. Vibhakar; Ex. 126, Test. Dr. Westhoff 814 (cervix is soft and easy to dilate due to infection, but uterus does not respond well to medication; prompt removal of pregnancy by D & E safer and quicker); Ex. 124, Test. Dr. Hammond 555-60 (uterus must be evacuated for chorioamnionitis; can evacuate uterus by labor induction, but D & E is better choice because (1) it is predictable; (2) the longer the mother stays pregnant, the sicker she will become and as the uterus contracts, bacteria within the uterus may inoculate the woman's bloodstream which, with prolonged labor, may cause life-threatening sepsis, particularly if infection is caused by gram negative bacteria; (3) the infected uterus does not contract well and may not be able to sufficiently contract to stop bleeding after the fetus is delivered; and (4) a D & E can be performed on an emergency basis, such as when premature rupture of the membranes occurs and vaginal flora gain access to the uterus and cause infection).)

Still others believe that medical induction may be contraindicated for some women because medications

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[86] Except for the underlying clotting disorder, this scenario and Dr. Hammond's response to it parallels that of Dr. Darney as discussed in his letter to Congress.

that induce labor, like misoprostol and other prostaglandins, may have adverse effects on patients with certain maternal conditions such as severe asthma. (Ex. 120, Test. Dr. Broekhuizen 506-07.) Further, the use of prostaglandins, such as misoprostol, has been associated with cardiac arrythmia and sudden death. (Ex. 123, Test. Dr. Frederiksen 1076.)

Some physicians believe that medical induction is contraindicated for a woman whose uterus is scarred by a prior cesarean section (particularly with a vertical incision) or myomectomey (removal of a benign tumor from the uterine muscle) because the uterus is prone to rupture at the site of the scar during medically induced labor. In contrast, a D & E does not stimulate strong contractions in the uterine muscle and does not present the risk of uterine rupture. (Ex. 121, Test. Dr. Chasen 1582-85; Ex. 120, Test. Dr. Broekhuizen 505-07 (medical induction contraindicated for woman whose uterus is scarred by a prior cesarean section or who has undergone prior uterine surgery; uterus is prone to rupture at the site of the scar during medically induced labor); Tr. 1749, Test. Dr. Lockwood ("there might be an advantage to vaginal abortion over medical [induction] abortion after 20 weeks, before viability, in a setting where there was a previous C section or other uterine surgery that had been performed"); Ex. 123, Test. Dr. Frederiksen 1079-80 & 1138 (when uterus is scarred, higher risk of uterine rupture with labor induction than with D & E because scars can open during induction process; D & E usually safer method of terminating second-trimester pregnancy in women who have undergone prior cesarean section, hysterotomy, or myomectomy); Ex. 122, Test. Dr. Creinin 712-14 (when upper portion of uterus is scarred, where contractions are the

strongest, induction abortion is contraindicated; D & E is wiser and safer method of terminating second-trimester pregnancy in women who have undergone prior cesarean section or myomectomy if incision was made in upper portion of uterus); Ex. 126, Test. Dr. Westhoff 815-17 (scarred uterus can rupture during induction abortion; hemorrhage can occur, and if uterus cannot be repaired, woman may have to undergo hysterectomy which eliminates her ability to have children in the future); Ex. 891, Test. Dr. Clark 2358-61 & 2407-08 (although there is no published data on the issue, it is reasonable to believe that dismemberment D & E is safer second-trimester abortion method for women with scarred uterus; no reason to believe D & E would present higher risk of uterine rupture in patients with prior uterine scar, but based on risk presented by uterine contractions at term, it is reasonable to believe contractions of labor induction may rupture uterus).)

Dr. Creinin believes that medical induction may also be contraindicated for a woman:

* *With liver failure and associated clotting disorders.* Induction is a very prolonged process, and bleeding occurs when the fetus passes through the birth canal and when the placenta separates. When the woman's ability to clot is compromised, an expeditious surgical procedure in a controlled environment is the medically appropriate abortion method. (Ex. 122, Test. Dr. Creinin 689-90; *see also* Ex. 126, Test. Dr. Westhoff 820 (prefers D & E over induction for women with bleeding disorders affecting clotting factors and platelets because missing clotting factors can be replaced during short duration of

D & E procedure, as compared with prolonged induction process).)

* *With significant underlying heart or respiratory diseases.* Labor induction prompts a fluid shift in the woman's body, medications must be administered, the induction process occurs over a prolonged period of time, and it may not be successful. When underlying heart and lung conditions exist, D & E is the preferred treatment for the health of the mother. (Ex. 122, Test. Dr. Creinin 714-15.) In Dr. Westhoff's practice, a patient's cardiologist may refer them to Dr. Westhoff for a D & E because prolonged labor is considered dangerous to their patients due to the change in dynamics of the blood supply. (Ex. 126, Test. Dr. Westhoff 819.) Anesthesia care during the D & E can protect the body's systems, including the lungs, while prostaglandins used to induce labor may cause bronchiospasm which interferes with the patient's breathing and oxygenation. (Ex. 126, Test. Dr. Westhoff 819.)

Dr. Vibhakar has had two cases where induction terminations were not the best medical option for the patient:

> I remember one case where the patient had atypical severe preeclampsia at about 19 weeks, and she had pulmonary edema and her respiratory status was worsening. She was already undergoing an induction termination procedure, but it was taking time, and it did not appear that she would deliver in the near future, so I was asked to perform a D & E. I did and she . . . clinically improved rapidly after that.

. . . .

> There was another patient who was approximately 20 weeks pregnant when she developed headache and loss of vision and was diagnosed with five to six centimeter intracranial hemorrhage due to a ruptured AVM, arterial venus malformation, and she wanted to terminate the pregnancy. She was counseled that she would be at risk of the AVM rebleeding should she carry the pregnancy to term and labor. She was also rather, the neuro surgeons at the University of Iowa did not want to treat the AVM. They did not want to ligate it or embolize it until after pregnancy. And my maternal fetal medicine colleague and the neurosurgeons in consultation with each other decided the best method for termination would be a D & E as opposed to an induction because it could be a more controlled procedure.

(Tr. 327-28, Test. Dr. Vibhakar.)

In cases where Dr. Cook performs an induction and the fetal head becomes trapped in the woman's cervix, he does not perform a "crushing procedure on the baby's head or some sort of suctioning or evacuation of the fetal brain contents." Instead, he waits several minutes to see if the woman passes the fetus on her own; administers medical agents like nitroglycerin to the mother that help relax the uterus; uses forceps on the head; or makes one or more Dührssen incisions[87] in

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[87] Dührssen incisions are "three surgical [incisions] of an incompletely dilated cervix, corresponding roughly to 2, 6, and 10 o'clock, used as a means of effecting immediate delivery of the fetus when there is an entrapped head during a breech delivery." *Stedman's Medical Dictionary* 887 (27th ed. 2000).

the cervix to allow the head to pass. If incisions are used, Dr. Cook sutures the incisions if they are bleeding, but if no bleeding is present, he does not suture the incisions in order to reduce the risk of adhesion formation. Dr. Cook views these cervical incisions as "more gentle" than dilation with osmotic dilators because "[i]t's a single incision that's done in a portion of the cervix with immediate repair"; cervical lacerations or tears are "observed frequently as part of the natural physiologic process of labor"; and damage caused by osmotic dilators that are placed into the "entire length of the cervical canal" creates a "zone of injury [that] goes to the entire cervix, not just to the area we are making an incision." (Tr. 1418-22 & 1462-63, Test. Dr. Cook.)

Dr. Broekhuizen opined that if bleeding is significant or the membranes have ruptured easily and early such that infection may result if the labor-induction process is prolonged, labor induction may be converted to a D & E for the safety of the mother. According to Dr. Broekhuizen, once bleeding and infection occur during a labor induction, antibiotic administration alone is not sufficient because the body cannot respond quickly enough to this treatment. Waiting for more dilation, administering antibiotics, or making Dührssen incisions are also not appropriate medical responses. Dührssen incisions inflict trauma to the cervix which can be repaired, but may present problems in future pregnancies. (Ex. 120, Test. Dr. Broekhuizen 531-34.) Labor induction may progress to the point that the fetus is living and partially delivered with the fetal head lodged at the internal cervical os. Under these circumstances, compressing the fetal skull to complete the abortion may be the best option. (Ex. 120, Test. Dr.

Broekhuizen 532-34, 551-52.) This situation may also arise from a spontaneous midtrimester miscarriage. (Ex. 120, Test. Dr. Broekhuizen 555-56.)

The fetus may be delivered intact and alive in an induction abortion. In Dr. Hammond's practice, if the fetus has even a remote chance of viability, the 24-hour neonatologist on site is called to provide assistance. However, in all cases, an abortion is not performed absent very good data indicating that the fetus is not viable. When it is born alive, it is kept warm or, if the mother wants to hold it, given to the mother until it dies. (Ex. 124, Test. Dr. Hammond 616-17.)

Dr. Shadigian's article analyzing available peer-reviewed abortion literature examined seven potential complications of abortion, which was defined as elective termination of pregnancy, including surgical methods and medical induction-subsequent spontaneous miscarriage, subsequent infertility, subsequent ectopic or tubal pregnancy, breast cancer, placenta previa, preterm birth, and psychological effects. (Ex. 631 & Tr. 1562.) The study concluded that induced abortions were not associated "in the aggregate" with ectopic pregnancy, subfertility (i.e., the ability to get pregnant after the abortion), or subsequent spontaneous miscarriages. The study also found that based on a review of population-based studies, induced abortion increases the risk of preterm birth in subsequent pregnancies by up to two times, and the more abortions a woman has, the higher the risk for subsequent preterm births. The article found notable the increased risk of preterm deliveries at 20 to 30 weeks of gestation after induced abortion "which is especially relevant because these are the infants with the most risk of morbidity and mortality upon which society expends so many re-

sources." (Tr. 1537 & 1542-50, Test. Dr. Shadigian; *see also* Ex. 126, Test. Dr. Westhoff 1790 (greater cervical dilation must be achieved for second-trimester induction abortion to accommodate delivery of the fetal head).) Dr. Shadigian is concerned that because her study focused primarily on first-trimester abortion procedures, showing a doubling effect of preterm birth in later pregnancies, "in the D & X procedure, we are talking a much greater size of the baby, and this baby being pulled through a partially-open cervix such that . . . the potential for damage to the cervix is much greater in a D & X procedure than it would be in a simple first[-]trimester procedure" and there could be "even more pre-term birth with second[-]trimester abortions or later gestational age ones." (Tr. 1549-50 & 1578, Test. Dr. Shadigian.)

According to Dr. Frederiksen, the history of abortion in this country proves that labor-induction techniques are riskier than D & Es. While the percentage of second-trimester terminations performed by labor induction has been decreasing, the proportion of those abortions performed by D & E has increased and with that change, the overall safety record of second-trimester abortions has improved. (Ex. 123, Test. Dr. Frederiksen 1066-67.)

vi. HYSTEROTOMY AND HYSTERECTOMY

Hysterotomy[88] and hysterectomy[89] are available abortion options that account for 0.01% of all abortions

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[88] A hysterotomy is an abdominal incision through the abdominal wall and uterus performed for the purpose of emptying the uterus. (Ex. 123, Test. Dr. Frederiksen 1077-78.) *See also Stedman's Medical Dictionary* 869 (27th ed. 2000) (a hysterotomy is an incision of the uterus). If performed before the fetus is at 23 to 24 weeks of gestation, the surgical method used for performing a

and 0.07% of second-trimester abortions performed in the United States. (Ex. 125, Test. Dr. Paul 46-47.) Dr. Broekhuizen explained that hysterotomy is a major surgery, and although it can be performed when induction and D & E procedures fail, it is a last option before 24 weeks. (Ex. 120, Test. Dr. Broekhuizen 508.) In Dr. Paul's opinion, the death rates associated with abortions performed by hysterotomy or hysterectomy are prohibitively high. (Ex. 125, Test. Dr. Paul 46-47.)

Dr. Frederiksen explained that, for midtrimester pregnancies, the hysterotomy incision must be made vertically, similar to a classical cesarean section, because the lower segment of the uterus is not yet present and, therefore, a horizontal lower segment transverse incision is not an option. As a result, as with classical cesarean sections, women who have undergone a hysterotomy should not go through labor to deliver future pregnancies. All subsequent pregnancies should be delivered by cesarean section. Labor induction for termination of any future second-trimester pregnancy also presents a 2.3% higher risk of uterine rupture and hemorrhage. (Ex. 123, Test. Dr. Frederiksen 1077-78.)

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cesarean section is called a hysterotomy. (Ex. 891, Test. Dr. Clark 2379-80.)

[89] A hysterectomy is removal of the uterus. *Stedman's Medical Dictionary* 867 (27th ed. 2000).

b. TYPES OF STUDIES

Joel D. Howell, M.D., Ph.D., received his medical degree from the University of Chicago in 1979 and his Ph.D. in history and sociology of science from the University of Pennsylvania in 1987. He completed his internship and residency in internal medicine at the University of Chicago hospitals, is licensed to practice in Michigan, and is board-certified in internal medicine. Dr. Howell is a professor at the University of Michigan in the Department of Internal Medicine, the Department of History in the College of Literature Science and the Arts, and the Department of Health Management and Policy in the School of Public Health. Dr. Howell directs the Clinical Scholars' Program, which is a two-year fellowship program for physicians in a variety of clinical specialties that teaches physicians how to conduct research benefitting the health of all Americans. He has lectured and published papers in peer-reviewed journals about the development of surgical techniques, and he serves as a manuscript reviewer and member of the editorial board for numerous medical journals. Dr. Howell has never performed an abortion, nor has he seen one being performed. (Ex. 97; Tr. 414-29 & 472, Test. Dr. Howell.)

Dr. George Mazariegos is a board-certified surgeon who received his medical degree from Northwestern University in Chicago in 1986. In 1991, he completed his internship and residency in general surgery at Michigan State University, after which he entered fellowships in critical care and organ transplantation at the University of Pittsburgh. Following his fellowships in 1994, Dr. Mazariegos became a faculty member at the University of Pittsburgh School of Medicine Department of Surgery, where he is now an associate profes-

sor of surgery and anesthesiology and critical care medicine and co-director of pediatric transplantation. He performs several transplant-related surgeries per week. Dr. Mazariegos is a fellow in the American College of Surgeons and serves as a reviewer of manuscripts dealing with pediatric transplantation for various journals. Dr. Mazariegos has never performed an abortion and observed less than five first-trimester abortions during medical school. (Ex. 890; Tr. 793-804, 839-40, Test. Dr. Mazariegos.)

Several physicians testified that clinical studies used to conduct medical research are prospective or retrospective and experimental or observational. Observational studies include case reports, case controlled studies, and retrospective cohort studies. "Case reports" are presentations or medical journal articles that describe one case or a series of cases over time. "Retrospective" studies look at something that has happened in the past. "Case controlled studies" are used to identify the cause of relatively uncommon events by comparing actual cases with controls having characteristics that might be responsible for causing the event. "Retrospective cohort studies" describe findings as to a particular group of people-like people living in a particular community or people who have undergone a particular surgical or medical procedure. (Tr. 433-36, Test. Dr. Howell; Tr. 907-10, Test. Dr. Bowes; Ex. 121, Test. Dr. Chasen 1622 (retrospective cohort studies are most common way to evaluate and compare surgical techniques).)

One type of experimental study is a "prospective randomized clinical trial" that looks at something from the present into the future where the "allocation of interest is assigned randomly" so that biases in the selec-

tion process are removed. (Tr. 436-37, Test. Dr. Howell; Tr. 908, Test. Dr. Bowes.) Such a study uses two or more groups and randomly assigns (often by computer) the groups to a specific treatment or intervention. The study participants have no choice on the treatment or intervention they receive. The participants are followed from the time of intervention forward. (Ex. 122, Test. Dr. Creinin 702-03.)

Randomized clinical trials eliminate bias by randomization and, because they are prospective, the person conducting the study can decide in advance what data needs to be collected and what outcome is of interest. This type of study is a "much more powerful statistical technique than simply looking for differences." The disadvantage of this type of study is that the benefits of doing the study must be worth the considerable costs involved. Drug studies are often conducted in this manner. (Tr. 440-44, Test. Dr. Howell; Tr. 828-29, Test. Dr. Mazariegos (discussing controlled prospective trials); Ex. 121, Test. Dr. Chasen 1667 (randomized trial would ideally allow for a better understanding of complications attributable to a procedure).)

Drs. Howell and Mazariegos explained that while the case series, retrospective cohort studies, and retrospective case control studies are simpler to perform because they do not require randomizing patients and they allow one to proceed as usual, they are limited in terms of range of patients and providers, they may reflect one's particular expertise or lack thereof, they suffer from potential bias in identification of confounders,[90]

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[90] For example, if you do not believe that smoking is related to lung cancer and you do not control for smoking in your study, you have "missed a potential confounder . . . and you would come up

and relevant information may not have been recorded on the subjects' medical charts. (Tr. 437-38, Test. Dr. Howell; Tr. 825-26, Test. Dr. Mazariegos (describing flaws of case series).)

Dr. Howell noted that unlike retrospective studies, prospective studies may involve alteration of the physician-patient relationship. A patient trusts a doctor to do what is best for the patient, while a study comparing two different treatment choices may conclude that one of the choices is dangerous. "And that's going to mean that some patients won't want to enroll and some physicians won't want to do the study." (Tr. 439-40, Test. Dr. Howell.)

Dr. Howell believes that surgical techniques are difficult to standardize for study purposes. Unlike a drug that is being studied that remains the same with each dose, surgical techniques vary because different operators have different skill levels, the same operator has different skill levels over time, and patient/surgeon interaction during surgery may cause the procedure to change or be done slightly differently in any given case. While the FDA monitors and manages the introduction of new drugs, there is no equivalent for the introduction of new surgical procedures. (Tr. 443-44, Test. Dr. Howell; *contra* Tr. 830, Test. Dr. Mazariegos (controlled trials in surgery not difficult to standardize because of varying skill levels of surgeons because all surgeons are expected to uphold certain standard, and it is the standard that is being tested, not the skill of the surgeon; including other institutions and surgeons can eliminate any possible bias).)

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potentially with a result that was erroneous." (Tr. 438, Test. Dr. Howell.)

> [A]sking patients to randomize themselves to surgical procedure[s] is asking them to have a very different sort of interaction with the surgeon than is the case for a drug study. . . . [T]he surgeon is asking the patient to agree to the surgeon being constrained in terms of what she or he might want to do, when they actually are in the course of performing that particular operation. And some patients . . . would be less likely to want to agree to that.

(Tr. 445-46, Test. Dr. Howell.)

Drs. Howell and Mazariegos identified "having power" as a challenge associated with conducting a study comparing two procedures that both appear, from initial study, to have very low complication rates; that is, the likelihood that the study will establish a clinically significant difference between the two procedures. When one expects to see major differences between two procedures, a smaller study would suffice, but when the differences between two procedures will be smaller, "you're going to need a huge number of patients, because otherwise, you're simply not going to be able to make that differentiation." It may also be difficult to justify continued investment of physician and patient time and money when both procedures have very low complication rates. (Tr. 448-52 & 460, Test. Dr. Howell; Tr. 834-36, 858, 864, Test. Dr. Mazariegos.)

According to Drs. Howell and Bowes, in order to "randomly allocate" patients to study "two treatment arms, be they drugs, surgery," clinical equipoise must exist-that is, the physician conducting the study cannot know that drug A or surgery A is better than drug B or surgery B or that either are better than a placebo. A physician cannot ethically enter patients into a study

comparing two treatments when the physician does not believe that equipoise exists. (Tr. 453-54, Test. Dr. Howell; Tr. 938, Test. Dr. Bowes (describing equipoise).)

Dr. Mazariegos testified that studies may be published in peer-reviewed journals, which are journals that require outside evaluation and critique of submitted data in an effort to assure that there are uniform standards for data presentation. He explained that data published in a peer-reviewed journal generally has "greater worth to clinicians" compared to medical literature that has not been subject to any sort of review process. The latter type of literature may suffer from a lack of accountability on the part of investigators who have failed to uphold certain standards of informed consent, as well as bias resulting from a lack of objective review of the process used to answer the question at issue, statistical methods, and use of control groups. (Tr. 821-23, Test. Dr. Mazariegos.)

Surgeons disagree about what is an acceptable variation of an existing surgical technique and what is a new or innovative surgical technique that warrants study by an institutional review board.[91] Whether a new surgical procedure is a "major modification" of an existing surgical technique is a "perceptual question on the part of the surgeon." (Tr. 852 & 881-82, Test. Dr. Mazariegos.)

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[91] Dr. Mazariegos explained that an institutional review board ("IRB") is a body that functions within a hospital setting to review investigations of procedures, devices, medicines, or new therapies. The board contains physicians from the relevant specialty and from other specialties. Physicians not affiliated with a hospital may submit potential protocols to the hospital's IRB for study and analysis. (Tr. 819-20 & 875-76, Test. Dr. Mazariegos.)

Drs. Howell and Mazariegos stated that if a case series or several case series have demonstrated the safety of a modification of a surgical technique, whether the modification would receive additional study depends on the extent of the modification and whether the modification produces significant outcomes as compared with the original surgical technique. Problems in studying surgical technique modifications include standardization, patient recruitment, and study design (i.e., defining an important question, finding an answer that will be useful to patients, and designing a study to accomplish those goals). (Tr. 447-49, Test. Dr. Howell; Tr. 831, Test. Dr. Mazariegos (only major surgical modifications should be subject to further study and peer review; major surgical modifications are those that "alter the risk to a patient in a perceptible . . . manner").) According to Dr. Howell, randomized clinical trials can be suitable for evaluating variations in surgical techniques if standardization, patient recruitment, and study design problems are solved. "It is often held up as a goal. It is rarely achieved." (Tr. 453, Test. Dr. Howell.)

Dr. Howell testified that in situations where a physician wishes to study a surgical procedure, but still wants to offer the procedure to his or her patients, observational studies like publishing the results of a case series and presenting the results at professional meetings are appropriate. (Tr. 458, Test. Dr. Howell.) Peer review and observational studies in retrospective reviews provide objective, reliable information about the risks and benefits of surgical procedures to guide surgeons as to the safety and efficacies of new procedures. Many studies in the surgical arena are retrospective in design and many retrospective reports regarding sur-

gery involve procedures performed at a single institution. (Tr. 866-67, Test. Dr. Mazariegos.)

Dr. Howell noted that the coronary artery bypass grafting procedure was studied only after the technique had been used on many patients.

> [The coronary artery bypass grafting procedure] was studied in the sense that when people first tried the different approaches, they took note of what happened. They took note of whether they saw an improvement in the patient or not. The technique rapidly expanded, and within . . . a decade of its being introduced, it was being performed on probably hundreds of thousands of patients. It was only after that point that systematic standardized trials began to be done. And when they were performed, there was a considerable amount of controversy about whether or not those trials needed to be done.

(Tr. 432-33 & 458, Test. Dr. Howell.)

Dr. Howell also testified that there are clinical procedures, such as removing fluid from a lung ("thoracentesis"), that are performed in varying ways, yet such variations have not been subject to clinical trials. Thoracentesis—a procedure performed daily in hospitals across the nation with a low, but not insignificant, rate of complications—can be done from the side or from the back, with ultrasound guidance, or with physical examination.

> [Thoracentesis] is learned by craft, by doing it side-by-side. And to the best of my knowledge, nobody has ever done a systematic study to say is it better to do it one way or the other way. Typically, you learn how to do it one way, as I did, and then you

> teach others how to do it that way, and maybe somebody does it slightly differently at another institution. And we see this all the time, particularly in people who are trained in different institutions work together. We see minor variations in the way that a procedure is done. It's very common.

(Tr. 460-61, Test. Dr. Howell.)

Dr. Howell characterized new surgical techniques that warrant further study as techniques that "represent[ ] a distinct shift from the way things were being done in the past; perhaps a different approach, perhaps a different intent of the operation and, again, the outcome would also differ." (Tr. 462, Test. Dr. Howell.) Assessing the safety of a new surgical technique requires passing a "much higher standard" than evaluating the safety of a variation of an established surgical technique when the technique and variation have initially been found to have a "similar safety record." (Tr. 462-63, Test. Dr. Howell.)

Defendant's witness Dr. George Mazariegos agreed that innovative surgical procedures that fall within a "gray zone" between a variation of a standard procedure and a unique departure from accepted standards should be reviewed in a "more flexible manner" than the formal IRB process, and that statistically significant results from a retrospective study of a surgical technique may not be available until the technique has been used in an appropriately large number of cases over a time period that could be years. (Tr. 869-70, Test. Dr. Mazariegos; Tr. 970-71, Test. Dr. Bowes (new procedure cannot be studied until it has been performed enough).)

Drs. Mazariegos and Bowes testified that once a physician obtains new data establishing the safety or effectiveness of a new surgical procedure, the data typically is disseminated in a peer-review setting, such as to colleagues at meetings, followed by a report in medical literature. If initial information suggests a possible role for a new therapy or procedure, "that would typically spur on the development of comparative trial." Some surgeons expect to see peer-reviewed studies of new procedures within one to two years, although there are exceptions to this standard, such as large studies that require follow-up and studies focusing on long-term benefits or risks. (Tr. 836-38, Test. Dr. Mazariegos; Tr. 912 & 966, Test. Dr. Bowes (once a procedure is introduced, "there comes a point at which you really need to confirm with some good evidence that it is a better procedure"; before a new procedure is used in medicine, it must be subjected to a randomized or case-controlled study before it becomes widely used).)

Dr. Howell believes the intact D & E "came about as a logical consequence of physicians doing the D & E procedure"; the intact D & E has developed "well within the bounds of currently-accepted medical practice" and consistent with the "very typical pattern" of surgical developments; and the intact D & E is not a new surgical technique, but a variation thereof. (Tr. 465-66, Test. Dr. Howell.)

Drs. Howell and Bowes opined that structuring a study comparing the intact D & E with other D & E variations would be "difficult." Conducting a retrospective study would be "useful," but would involve locating enough case files that contain the necessary information. Prospective studies would involve standardizing the procedures being compared; locating surgeons and

women willing to perform only the assigned procedure "even if, in the course of performing the procedure, [the surgeon] might wish to do it the other way"; and locating enough participants in order to find any meaningful difference in the risk of the two procedures. (Tr. 467-68 & 470, Test. Dr. Howell; Tr. 939, Test. Dr. Bowes (retrospective study comparing intact D & E to D & E or other abortion method difficult, but possible).)

In Dr. Howell's opinion, it would be "extraordinarily difficult" and undesirable to design a randomized prospective study comparing the intact D & E and the D & E because the knowledge gained from such a study would be minimal when "the risks [of the two procedures] are already low enough. . . . on both sides, and we know the problems of doing this sort of a study would be considerable." (Tr. 468-69, Test. Dr. Howell; Tr. 861, Test. Dr. Mazariegos (may be difficult to get sufficient number of patients who would agree to be randomized between two treatment options or surgical procedures); Tr. 933-34 & 964-65, Test. Dr. Bowes (although difficult, a prospective or retrospective study could be designed comparing the intact D & E with the traditional D & E; a randomized prospective study comparing inductions to D & Es would be difficult to do in the United States where induction is not the norm).)

Dr. Creinin has been the principal investigator in 8 prospective randomized trials, and has been involved in more than 20 others. He believes a prospective randomized trial comparing second-trimester abortion techniques would be unfeasible, unreasonable, and impossible to accomplish (Ex. 122, Test. Dr. Creinin 703-05) because:

* His experiences with similar first-trimester studies have been unsuccessful.

1) Dr. Creinin began a prospective randomized trial comparing medical and surgical abortions in women with fetuses of up to seven weeks of gestation. To be included in the study, and after receiving counseling, the women had to state they had no preference as to which method was performed. Dr. Creinin's goal was to have 100 study participants. After two years, the study was stopped; 1,000 women had been interviewed for the study but only 50 agreed to participate. With further follow up, only 15 of the 50 really had no preference as to the method of abortion performed. (Ex. 122, Test. Dr. Creinin 703-05.)

2) Dr. Creinin was involved in an NIH study of treatment of early miscarriage. Four respected medical centers were awarded a contract to study medical versus surgical treatment of miscarriage with a goal of soliciting 800 participants over 1 1/2 years. After 2 years, only about 600 women had agreed to have their treatment randomized. (Ex. 122, Test. Dr. Creinin 707.)

* Dr. Grimes did a study to determine if a randomized controlled trial of labor induction versus D & E was feasible and, based on the lack of willing participants, concluded such a study was not feasible. Dr. Creinin believes Dr. Grimes is "an incredibly well-respected mentor, researcher, teacher. And I can think of nobody who would be a greater example of how to construct such a study. And if they couldn't find it feasible there . . . I can't see this as being fea-

sible anywhere." (Ex. 122, Test. Dr. Creinin 707-09.)

* A very large number of participants would be required in a randomized study of induction versus D & E because both induction and D & E are safe second-trimester abortion methods. With a 1% risk factor, there would need to be 5,000 participants in both groups to reach a statistically significant conclusion; for a 2% risk factor, 2,500 participants would be needed in both groups. (Ex. 122, Test. Dr. Creinin 705-07.)

* The available pool of first-trimester abortions is far greater than second-trimester abortions, yet Dr. Creinin's similar first-trimester study failed for lack of participation. (Ex. 122, Test. Dr. Creinin 705.)

There are no randomized clinical studies comparing the safety of intact and dismemberment D & Es. In Dr. Paul's opinion, such a study would not be feasible or warranted because: (a) the intact D & E is a variant of the D & E and probably does not merit a separate study; (b) the occurrence of an intact D & E is hard to predict at the outset; (c) a very large number of study participants in each group would be required because the complication rates are so low; and (d) the percent of second-trimester abortions, and therefore the available pool to draw from for a study, is small. (Ex. 125, Test. Dr. Paul 89-90 & 107.)

Dr. Lockwood believes that the safety of the intact D & E procedure could be studied by randomized trial to identify possible complications caused by the procedure:

> I think that patients would have to be fully informed that they were going to be part of a study. I think that strict guidelines that led to differing degrees of cervical dilation would have to be employed, and that patents would have to be randomized at the intent[-]to[-]treat point. So that even if the procedure turned out to be . . . a D & E, they are part of the intact D & X group, and vice-versa. And having done all that, then appropriate comparisons could be made of blood loss, procedure time, complication rate, and so forth.

(Test. Dr. Lockwood 1707.)

Dr. Creinin pointed out that prospective randomized trials have been successfully performed comparing elective versus routine episiotomies and comparing cesarean section versus vaginal birth for breech-presentation term deliveries with a study group exceeding 2,000 women. (Ex. 122, Test. Dr. Creinin 775-76.) However, these were not abortion-procedure studies. Dr. Creinin testified that the breech-delivery study was government-funded, the data indicates that women seeking abortions do not want to be randomized, and it is difficult to standardize intact versus dismemberment D & E procedures when, irrespective of the doctor's intent at the outset, the procedure actually performed depends on the unpredictable factor of cervical dilation. (Ex. 122, Test. Dr. Creinin 778-80.)

"[N]o one has ever done a study to show what the optimum dilation is of the cervix to reduce trauma," and these types of safety issues could be studied by a prospective randomized blinded trial or a retrospective case-controlled study comparing types of abortion procedures, according to Dr. Shadigian. From her experi-

ence in doing a prospective "term breech trial," Dr. Shadigian believes women would agree to be randomized to various comparison groups because "women undergoing the D & E or D & X or medical induction would, with good informed consent, be able to say, . . . Doctor, if you don't know what's safer, I want my care to be part of something bigger than myself so I can help other women." (Tr. 1531-34, Test. Dr. Shadigian.)

Dr. Broekhuizen testified that if one wanted to study whether cervical dilation increases the risk of cervical incompetence, a group of women would have to be monitored long-term to assess their subsequent pregnancies. The larger the group of women followed, the more reliable the study. However, it is probably impossible to conduct such a study in Dr. Broekhuizen's view. A retrospective study would require review of records from several institutions and physicians, and would therefore incorporate the inconsistencies and variations of the different physicians. It could be set up only with the cooperation of multiple institutions operating under a very tight protocol so that data collection and reporting was internally consistent. Dr. Broekhuizen is not aware that this type of study has been done. Dr. Broekhuizen thinks that a randomized clinical trial comparing induction abortions and the D & E would be impossible because patients have very strong feelings about the abortion procedure performed and would not want to be randomized for scientific study. (Ex. 120, Test. Dr. Broekhuizen 615-17.)

To establish the safety of the intact D & E method of abortion, Dr. Lockwood would like to see "retrospective studies of those centers that have large experience, preferably comparing it to D & Es and doing [statistical analysis] to control for variables such as parity, cervical

dilation, gestational age." He would like to "get some sense as to whether or not there is a lower incidence of . . . hemorrhage, perforation, the occurrence of lower hematocrits, decreased procedure time. The various end points that theoretically appeal to those who do it." (Test. Dr. Lockwood 1707.)

Dr. Lockwood also believes that retrospective chart reviews would be helpful in analyzing the safety of the intact D & E procedure. (Tr. 1706-08, Test. Dr. Lockwood.) A retrospective cohort study may be used to compare intact and dismemberment D & Es, but only if the doctor recorded which variation of the D & E was actually accomplished. Currently this specificity in charting is not usually done in the medical community. (Ex. 125, Test. Dr. Paul 108.) Descriptive case studies by physicians who have utilized the intact D & E procedure have "some value," but such studies are generally used "as the basis for then pursuing additional studies; whether they are retrospective . . . cohort studies or case controlled studies, or actual randomized clinical trial." (Tr. 1708, Test. Dr. Lockwood.)

The defendant's witness, Dr. George Mazariegos, agrees that "stifling innovation would be bad for medicine" and there are some cases in which a clinician may believe there is enough data to support the introduction of a surgical process without conducting a randomized controlled trial. (Tr. 867-69, Test. Dr. Mazariegos.) However, Dr. Mazariegos cautions that when a small universe of physicians believes there is no appreciable risk in performing a certain surgical procedure, like the intact D & E, compared with an existing surgical procedure, like the D & E, "until there is either an outside body of review or until there is a demonstration of the safety efficacy of a procedure . . . there exists such a

high likelihood of bias that it's impossible to draw a conclusion to support that without some type of peer review literature to support that or some type of outside review that would be more objective." (Tr. 882-83, Test. Dr. Mazariegos; *see also* Tr. 1528-29, Test. Dr. Shadigian (case reviews like Dr. Haskell's 1992 paper not sufficient basis for evaluating safety of new procedure because designers of procedures have a vested interest in their technique and are biased toward safety; case reviews and presentations/discussions at national meetings are "initial steps" which should be followed by a "series of evidence-based studies" in order to make conclusions regarding general safety of a procedure).)

Dr. Westhoff believes that intuition is not an accepted method of clinical analysis. (Ex. 126, Test. Dr. Westhoff 975.)

c. STUDIES[92]

i. MCMAHON

A paper prepared by Dr. McMahon and presented on April 2, 1995, to the National Abortion Federation was received into evidence as Plaintiffs' Exhibit 64. The paper, entitled "Intact D & E, The First Decade," explains in great detail Dr. McMahon's experience in performing the procedure he called "intact D & E" from June of 1983 through February of 1995. The paper indicates that he would sometimes convert the fetus to a footling breech and sometimes take the fetus as he

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[92] The various studies discussed below were received, along with other evidence, "[n]ot to prove that these articles are true or not true, but one, to prove or disprove the existence of a substantial body of medical opinion or to prove or disprove questions related to the Congressional effort to ascertain the true facts." (Tr. 1626.)

found it, depending upon whether there was a "[l]ongitudinal lie, calvarium presentation" (head-first), "[l]ongitudinal lie, breech presentation" (feet-first), or "[t]ransverse/oblique lie, various presentations" (sideways or at an angle). (Ex. 64, at CH0000501-02.)

Dr. McMahon's paper gives a clear explanation of why he performed the intact D & E procedure:

Intact vs. Disruptive D & E

Why intact? Why should a surgeon decide to embark upon a plan that is tedious, time consuming and logistically difficult?

Certainly, if the pregnancy involves an unusual fetal flaw, the dysmorphologist, geneticist and perinatologist would much prefer a specimen in which the *in situ* relationships of the organs are preserved. This allows, with the exception of the central nervous system, for getting complete and accurate information from the post-mortem examination.

It is often the patient[']s preference, in that it's less offensive to their sensibilities. Also, if they want to hold or, just spend some time with their child, they can.

Staff turnover drops when the usual result is that the fetus comes out whole rather than disrupted.

All fine reasons, but insufficient to make such significant and burdensome changes in one[']s surgical approach. However, the evidence, although inconclusive, is beginning to suggest that this may be a safer approach, especially in the last half of pregnancy. Also, it is an approach that may be easier to

teach. It may be less dependent upon requiring the attendance of a physician with inordinate talent in the blind handling of a large grasping forcep inside a very vascular uterus.

IDE is different in that it forces the surgeon to analyze the situation and arrive at a plan based upon the analysis. Standards of dilatation must be set. The intact D & E is not done by protocol that is derivative of the characteristics of the average cervix. The extraction isn't done because it is Wednesday and that is the day when the D & E surgeon is scheduled to work. Something better guides our actions. It is the *cervix* that is finally sovereign.

DIC is much less of a problem using this technique because this new human genome is not being morsalized and shedding its foreign proteins into the mother's vascular system. Tissue thromboplastins in the fetal dermis probably escape during extraction, but perhaps what is the main culprit-the central nervous system—is gone before the calvarium begins its exit.

In reviewing charts for doctors who have had complications and then subsequent legal problems, I have seen several recurring themes. But, one stands out. The surgical summary lists the fetal parts as they are removed. The calvarium is the last to be extracted. In pursuing this part, the doctor describes sensing it being within the jaws of the forcep only to have it escape as he/she attempts to grasp it. Trying and trying and failing each time causes the bleeding, inexorably, to increase. The doctor feels the frustration gradually giving over to desperation. Finally, the instrument leaves the con-

fines of the uterine cavity. The catastrophe commences.

This scenario never occurs with intact D & E. The surgeon knows the spacial relationship of the part coming out of the external os because it is anatomic. The calvarium never slips out of one[']s grasp, because it is always attached. Control is maintained throughout the surgery.

(Ex. 64, at CH0000506-08.)

Dr. McMahon stated his conclusion in this way:

The bottom line . . .

The trauma of D & E derives from force of two types:

1. Cervical expansion

2. Traction of removal

Since it is through force that we cause harm, we must seek to balance these two forces to minimize trauma.

Begin by setting standards for cervical dilatation for each length of gestation. Oversee the implementation of these standards by methodically measuring and recording cervical dilatation at each surgical encounter, but most especially prior to extraction.

So what is the message of this survey?

— Is it a tedious approach to D & E? Yes, two dilations per day are difficult to schedule.

—Does it take too long? No, the average is 48 hours to complete the largest cases. In fact, beyond 30 weeks it trends downwards towards 40 hours.

—What about mechanical dilatation? Many surgeons "augment" the diameter that the passive dilatation has produced just prior to performing the extraction. Does this compromise future cervical competence? We have no good evidence that it does.

Certainly this survey tells us that if one perseveres with the cervix and waits until the ideal diameter is reached, the extraction is much less sanguineous, and it is easier.

When I describe this technique to other D & E surgeons, the greatest appeal is that it avoids the excruciating experience of chasing the calvarium. To repeatedly sense it between the jaws of your forcep only to feel it slip away as you attempt to grasp it, is not something that one wants to re-visit.

Is intact D & E better than the classical disruptive D & E? It depends upon the circumstances. Late in pregnancy, it may be the preferred method. Additional data is necessary. Although it is not the panacea that we all seek, it is yet another tool for us to help our patients.

(Ex. 64, at CH0000511-12.)

ii. CHASEN

Plaintiffs' Exhibits 27 and 28 are a peer-reviewed article by Stephen T. Chasen, et al., entitled *Dilation and evacuation at >20 weeks: Comparison of Operative techniques*, 190 Am. J. Obstet. & Gynecol. 1180 (2004), and a chart representing underlying data. This article

describes a retrospective cohort study[93] comparing patients who underwent the intact D & E and patients who had the traditional D & E. The objective of the study was to describe a large series of patients who had a D & E at 20 weeks or beyond, look at the characteristics of these patients, and compare the outcomes based on which variation of D & E was used. (Ex. 121, Test. Dr. Chasen 1613.)

The study began in March 2003 and was completed in July or August of 2003.[94] It was a retrospective co-

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[93] The study was approved by the hospital's institutional review board, a panel of physicians and lay persons that ensures that any research undertaken is ethical and protects the patients' interests. (Ex. 121, Test. Dr. Chasen 1614 & Sub-Ex. 30.)

[94] The manuscript was complete in late August or early September 2003 and was sent to the Journal of Obstetrics and Gynecology, an ACOG publication. It was rejected in October 2003. One reviewer deemed the manuscript vitally important and another stated it warranted publication with major revisions. One reviewer believed the terminology "dilation and extraction with disarticulation" was not an appropriate way to describe the non-intact D & E. The terminology was changed. Another reviewer believed Dr. Chasen was too conclusive when the article stated "Dilation and evacuation with intact extraction is as safe as dilation and extraction with disarticulation after 20 weeks' gestation," and claimed the study did not prove the intact D & E was safe, but only that there were no obvious differences in safety between the intact D & E and the dismemberment D & E. The conclusion was changed, but not in response to the reviewer. The conclusion was reworded to note that the outcomes of the two procedures were similar, thereby including not only safety issues, but issues related to subsequent pregnancies. The manuscript was resubmitted and tentatively accepted for publication in December 2003. (Ex. 121, Test. Dr. Chasen 1658-60, 1665, 1668, 1697.) Dr. Chasen did not mention to the Journal of Obstetrics and Gynecology that he was a plaintiff in a pending suit challenging the Partial-Birth Abortion Ban Act. (Ex. 121, Test. Dr. Chasen 1668.)

hort study based on medical records of the New York Weill Cornell Medical Center from 1996 through June 2003. Records from 1996 through May 2000 had previously been compiled for a different study, and the additional available data from May 2000 through June 2003 was added to the database. The study compared 383 cases where a D & E was performed at or beyond 20 weeks of gestation and placed these cases in two groups: 263 cases involved dismemberment D & E and 120 cases involved the intact D & E procedure. If a forceps was used, the procedure was defined as a dismemberment D & E. The complications identified included the requirement of a blood transfusion, the requirement of suturing a laceration, an unplanned hospital admission, readmission to the hospital, perforation of the uterus, and admission to intensive care. The individual patient characteristics noted included age, obstetric history, whether the patient had a prior cesarean section, gestational age, and the indication for the D & E. (Ex. 121, Test. Dr. Chasen 1615-25 & 1652-53.)

Dr. Chasen's study compared outcomes of these two groups of patients with regard to surgical complications, amount of bleeding, cervical lacerations, and infections. A certain number of the patients who had subsequent pregnancies were then evaluated regarding premature birth. The study found no difference in the complication rate between the two groups (5%) and no statistically significant difference in the incidents of premature birth. (Exs. 27 & 28.)

Comparing D & E and "intact dilation and extraction," the authors found:

> Outcomes appear similar between patients undergoing dilation and evacuation and intact dilation and

> extraction after 20 weeks' gestation. Subsequent obstetric outcomes are similar between the two groups. The technique for surgical abortion should be determined by the physician based on intra-operative factors.

(Ex. 27, at SC0034.)

The authors of the Chasen study added:

> Our approach of performing intact dilation and extraction when possible is intended to minimize the use of forceps in extracting the fetus. We believe that use of forceps to grasp the fetus can cause inadvertent trauma to the uterine wall. At these gestational ages, evacuation of a fetus can require multiple insertions of forceps, and intact dilation and extraction avoids this. Though we believe our low complication rate validates our approach, we acknowledge that the retrospective nature of this study precludes us from concluding with certainty that intact dilation and extraction prevent adverse outcomes.

(Ex. 27, at SC0040-41.)

The data from physicians who performed only dismemberment D & Es and not intact D & Es was not included in the Chasen study. The D & Es of two physicians were included in the study. One-third of those were performed by Dr. Chasen. (Ex. 121, Test. Dr. Chasen 1653.)

The complication rates for the two groups were identical, but the serious complications (uterine perforation, amniotic fluid embolus, sepsis, and pulmonary embolus) all occurred with dismemberment D & E. These complications could not have been avoided by

performing an intact D & E because that procedure was not feasible on those patients. There is generally a higher rate of complications associated with abortions performed at later gestational ages. However, in the Chasen study, the rate of complications was the same for the intact D & E procedure (average gestational age of 23 to 24[95] weeks) compared to the dismemberment D & E procedure (average gestational age of 20 to 21 weeks). Although not proved with certainty by the study data, Dr. Chasen believes that since each serious complication occurred in the dismemberment D & E group, and the intact D & E group did not have a higher complication rate despite the higher risk of complications due to greater gestational age,[96] the intact D & E has safety advantages over the dismemberment D & E. (Ex. 121, Test. Dr. Chasen 1627-30, 1632-34, 1661, 1665-66.)

Sixty-two of the 383 women had subsequent pregnancies that were documented in the hospital's medical records. Four of these women delivered prematurely in a subsequent pregnancy. Two had previously had a dismemberment D & E (2 of 45, or 4% to 5%), and 2 had an intact D & E (2 of 17, or 11 to 12%). The 2 women with a history of a prior intact D & E aborted their fetuses because the woman's membranes had ruptured or there was considerable premature cervical dilation. Based on this history, both women were at a high risk of premature delivery in a later pregnancy irrespective of having a D & E. Though both delivered prematurely

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[95] The study population at 24 weeks included several anencephalic fetuses. (Ex. 121, Test. Dr. Chasen 1647.)

[96] According to Dr. Chasen, between 21 and 23 weeks, the fetus grows 50% larger. This growth increases the risk of complications during abortion. (Ex. 121, Test. Dr. Chasen 1694.)

in a subsequent pregnancy (32 weeks and 35 weeks), these pregnancies were considered highly successful in light of the women's underlying risk factors for premature birth. The remaining 15 women who previously had an intact D & E procedure did not have underlying obstetric risk factors for premature delivery, and all 15 delivered at term. Dr. Chasen believes that although the statistical sampling is small, the data from his study indicates women who were not considered at high risk for premature delivery in a later pregnancy did not have a preterm birth following an intact D & E procedure. (Ex. 121, Test. Dr. Chasen 1630-32.)

Dr. Bowes found the Chasen study limited because the number of patients participating in the study was too small to conclude to a statistically valid degree that there was no difference in outcomes; the authors did not clearly describe their patient follow-up procedures or how they decided which patients would receive which procedure; and the patients in each group varied in age, gestation at the time the abortion was performed, and indications for which the abortions were performed, and these factors were not adjusted for using regression analysis because the sample size was too small. Dr. Bowes believes the Chasen study "does not prove the superiority of one of these procedures over the other." (Tr. 926-31, Test. Dr. Bowes.) However, the Chasen study establishes the general level of complications in two groups of patients, which is "important information to have" in designing a prospective randomized controlled trial. Dr. Bowes testified that a retrospective study like Chasen's is "often the first step in the process towards a randomized controlled trial." (Tr. 979, Test. Dr. Bowes.)

Dr. Sprang opined that the Chasen study involved such small numbers in terms of number of patients, complications, and subsequent pregnancies that, although indicating trends, the numbers "didn't have any power. . . . The study [had] so few cases that you can't say anything is statistically significant." (Tr. 1157-60 & 1225-26, Test. Dr. Sprang.) Further, "the conclusions they came to didn't seem consistent . . . with the data." (Tr. 1222, Test. Dr. Sprang.)

Dr. Lockwood testified that the Chasen study "suggests [the intact D & E method of abortion is] safe." (Tr. 1705, Test. Dr. Lockwood.) However, the study is not "adequate to demonstrate that the D & X procedure has safety advantages over the procedure of D & E by dismemberment" because "the study essentially shows that [the two procedures] are remarkably similar in their outcomes. The procedure times were literally identical, and the blood loss was literally identical, and the occurrence of complications was virtually identical." (Tr. 1719, Test. Dr. Lockwood.)

According to Dr. Lockwood, the size of the patient groups used in the Chasen study (120 and 263) are "not trivial," but "[t]he study is obviously underpowered, doesn't have adequate numbers to rule out differences in grave complications; death, perforation, which would require many, many more patients than this. But it gives us a good sense that the overall rate of standard complications, immediate short-term complications were very similar in the two groups." (Tr. 1720-21, Test. Dr. Lockwood.)

In contrast, the study does not tell us "much" about potentially significant long-term complications. Dr. Lockwood stated that the Chasen study found a disparity regarding the long-term complication of preterm

birth for the intact D & E (11.8%) and the traditional D & E (4.4%). However, this disparity is "not statistically significant" and there were additional risk factors in the intact D & E group for subsequent premature delivery.

> [F]ormally as a clinician researcher, I wouldn't draw any conclusions from it. Would this provoke me to want to do additional studies? Absolutely. Does it sort of already fit into my bias about the procedure as an expert on prematurity? Yes, it does. Would it make me prohibit [the procedure's] use . . . [n]o, but it certainly would prompt me to want additional studies [regarding the potential preterm birth complication].

(Tr. 1722, Test. Dr. Lockwood.)

Dr. Lockwood pointed out that the risks of morbidity from abortion, while very low, increase each week of gestation. In the Chasen study, the median gestational age of women receiving intact D & Es was 23 weeks, while the median gestational age of women receiving a traditional D & E was 21 weeks. While one would expect that the complication rates of the intact D & E group would be higher, they were not. (Tr. 1761-62, Test. Dr. Lockwood.)

The Chasen study (published May 2004) confirms Dr. Westhoff's impression and conforms to her clinical experience that intact D & E is safer than dismemberment D & E. (Ex. 126, Test. Dr. Westhoff 840.) In fact, Dr. Westhoff believes Chasen's conclusion, that dismemberment and intact D & E have similar complication rates, is too conservative. She notes that, in the Chasen study, intact D & Es were performed on patients whose fetuses were at a greater gestational age than the dismemberment D & E group. A higher rate

of complication was expected in this later gestational group, yet with intact D & E, that group's complications were kept at a lower gestational age rate of risk. She believes this indicates intact D & E is actually safer than dismemberment D & E. (Ex. 126, Test. Dr. Westhoff 855.)

However, Dr. Westhoff acknowledges that the Chasen study is an observational study and not a random clinical trial. The study sample size was small, the study groups for intact and dismemberment D & E were not equal in size, and the study groups involved procedures done at different mean gestational ages. Dr. Westhoff opined that these factors reduce the value of the Chasen study's statistical comparisons and conclusions. (Ex. 126, Test. Dr. Westhoff 975-79.)

Dr. Clark believes that the Chasen study proves the intact D & E is not safer than the dismemberment D & E. He believes the study shows a threefold increase in preterm birth in women who have had an intact D & E (Ex. 891, Test. Dr. Clark 2388-89 & 2394), and may indicate that the extent of dilation in the intact D & E increases the risk of premature birth. (Ex. 891, Test. Dr. Clark 2311 & 2386.) He states that the increase in preterm birth described in the Chasen article and related to intact D & E is "dynamite waiting to go," and believes that once published, this information ethically obligates doctors to warn women of the long-term complication of preterm birth before the woman consents to an intact D & E. (Ex. 891, Test. Dr. Clark 2390-92.)

Dr. Clark acknowledges, however, that a woman who has previously experienced a preterm delivery is at a higher risk of preterm delivery in later pregnancies. (Ex. 891, Test. Dr. Clark 2412.) Based on their underlying history discussed in the Chasen article, the

two women in the intact D & E group who experienced subsequent preterm delivery were at a higher risk of preterm delivery irrespective of whether they had an intact D & E—that is, both women already had a risk of preterm delivery before undergoing any abortion procedure. (Ex. 891, Test. Dr. Clark 2412, 2427-29 & 2430.) He further acknowledges that, based on the statistical analysis set forth in the Chasen article, there is no statistical difference in the rate of preterm birth associated with intact versus dismemberment D & E. There is a 30% chance the differences seen were based on chance alone. (Ex. 891, Test. Dr. Clark 2425.)

iii. GRIMES

Plaintiffs' Exhibit 44 is a report authored by David A. Grimes and others entitled *Mifespristone and misoprostol versus dilation and evacuation for midtrimester abortion: a pilot randomised controlled trial*, III Brit. J. Obstet. & Gynecol. 148 (Feb. 2004). The report describes the feasibility of mounting a randomized controlled trial comparing midtrimester abortion using two drugs, mifepristone and misoprostol, and midtrimester abortion using dilation and evacuation (D & E) with laminaria.

This study was discontinued at one year because the individuals conducting the study had difficulty recruiting people into the medical abortion group. "Of 47 women eligible for the trial, 29 (62%) declined participation, primarily because of a preference for D & E abortion." (Ex. 44, at 148.) The authors concluded that "most women are unwilling to participate if D & E is available outside the trial." (Ex. 44, at 153.)

Of the 18 women remaining in the trial, 9 received the mifepristone-misoprostol method and 9 underwent

a D & E. The authors found that "[c]ompared with D & E, mifepristone-misoprostol abortion caused more pain and adverse events, although none was serious." (Ex. 44, at 148.) The study described its results only as "hypothesis-generating" and potentially useful in planning a larger randomized controlled trial. The authors noted that such a trial would be difficult to mount in the United States, and recommended that further study be conducted in a setting where labor-induction abortion is the norm, such as Europe or Asia. (Ex. 44, at 152-53.)

iv. AUTRY

Plaintiffs' Exhibit 19 is an article by Autry, et al., *A comparison of medical induction and dilation and evacuation for second-trimester abortion,* 187 Am. J. Obstet. & Gynecol. 393 (2002). This peer-reviewed article describes a retrospective study of 297 women who underwent either D & E or medical abortion. The study concludes that D & E is the safest method of second-trimester abortion. Specifically, the overall complication rate was significantly lower in patients who underwent dilation and evacuation than in patients who underwent medical abortion (4% vs. 29%). The article concludes that misoprostol is safer than other methods of medical abortion and that maximal use of laminaria will decrease complication rates in surgical abortion.

Some witnesses criticized the Autry study because many of the patients in the study lacked follow-up analysis and one of the defined complications that accounted for 77% of the study's complications was retained products of conception that required a D & C, which is not a complication in Dr. Sprang's view, but an inherent part of the procedure. (Tr. 1136-37, Test. Dr. Sprang; *see also* Tr. 1371-74, Test. Dr. Cook (disagreeing with Autry study results because retained placenta

is not complication, but normal result of medical induction; other complications were similar between the two procedures); Tr. 1557-61, Test. Dr. Shadigian (discrediting study due to retained placenta as complication; study not randomized and unclear if authors were blinded; gestational age for induction and D & E groups differed by two weeks).)

v. PAUL

Plaintiffs' Exhibit 70 is *A Clinician's Guide to Medical and Surgical Abortions*, Chapters 4-16 (1999), by Maureen Paul, et al. This is a guide for abortionists edited by Maureen Paul, M.D., who was then an associate professor of obstetrics and gynecology at the University of Massachusetts, and Medical Director, Planned Parenthood League of Massachusetts, and four other doctors, including E. Steve Lichtenberg, Lynn Borgatta, David A. Grimes, and Phillip G. Stubblefield. At the time, Lichtenberg was the Medical Director at the Albany Medical-Surgical Center. Borgatta was an associate professor, Department of Obstetrics and Gynecology, Boston University School of Medicine. Grimes was a clinical professor in the Department of Obstetrics and Gynecology at the University of North Carolina School of Medicine. Stubblefield was a professor and Chair of the Department of Obstetrics and Gynecology at Boston University School of Medicine.

Chapter 10 of the guide, entitled "Surgical Abortion After the First Trimester," is authored by W. Martin Haskell, Thomas R. Easterling, and E. Steve Lichtenberg. In that chapter, the authors extensively discuss the banned procedure.

The authors first state:

When possible, intact delivery in pregnancies over 18 weeks reduces the number of instrument passes necessary for extraction. During the second trimester vertex, breech, and transverse/compound presentations occur with roughly equal frequency. Below are some suggestions for operative strategies for each of these presentations.

Vertex Presentation. The key to delivery of a vertex presentation is achieving collapse of the calvarium. A variety of methods are used for this purpose, depending on the calvarium's firmness and accessibility. They include breaching and compressing the calvarium with the forceps' jaws, inserting a finger through a fontanel or along a suture line, or piercing the calvarium with a sharp instrument, such as a tenaculum or a large-bore needle. Decompression using attached suction is sometimes necessary. When cervical dilation is adequate but not generous, numerous instrument passes may be necessary to collapse and control the calvarium. Rotating the grasped calvarium as it passed through the cervix facilitates safe removal. When the fetus is compressed tightly against the cervix, freeing upper extremities affords extra space. Once the thorax is grasped, rotating the torso often frees the remainder of the corpus.

Breech Presentation. The signal maneuver for facilitating breech delivery is obtaining control of a lower extremity. With frank breech presentation, the surgeon's fingers or an instrument can be used to disentangle a lower extremity. Rotation of this extremity usually frees the second lower extremity. An intact extraction may be possible using a

Mauriceau-Smellie-Veit maneuver, as follows: Grasp the iliac crests, draw the torso downward until the scapulae emerge, then rotate the thorax to disentangle each upper extremity. If the cervix is compliant, the provider can deliver the uncollapsed calvarium by lifting the torso upward. Because this maneuver carries a small risk of cervical laceration, collapsing the calvarium is usually preferable.

Transverse/Compound Presentation. The advantage of ample dilation is nowhere more evident than in the case of transverse and compound presentations. Extraction is greatly facilitated if the provider can reposition the fetus into breech or vertex presentation digitally or instrumentally. Uterine palpation, digital examination, or ultrasonography may help assess fetal lie. Failing conversion, often the only option is disarticulation of an upper extremity and sequential deconstruction. Deconstruction is the usual recourse when a back-down transverse lie cannot be converted. With a back-up transverse lie, control of a lower extremity can convert the presentation to breech.

(Ex. 70, at 135 (footnotes omitted).)

Later, the authors extend their discussion on the banned procedure, giving reasons for its use, thoroughly discussing Dr. McMahon's experience as set forth in his paper, "Intact D & E, The First Decade," and also discussing Haskell's experience. They write:

Intact Dilation and Evacuation

The intact D & E procedure combines longstanding obstetrical practices for delivery of advanced, compromised pregnancies with modern

techniques of cervical dilation. The aim of intact D & E is to minimize instrumentation within the uterine cavity and achieve vaginal delivery of an intact fetus. Intact D & E is used as a method of second trimester abortion and, in the case of compromised pregnancies, as a technique for third trimester terminations. Intactness allows unhampered evaluation of structural abnormalities and can be an aid to patients grieving a wanted pregnancy by providing the opportunity for a final act of bonding.

Generally, cervical dilation is accomplished with multiple, serial osmotic dilators over 2 days or more. The goal is to achieve sufficient dilation to extract the largest part of the fetus, the bitrochanteric diameter of the pelvis, which is approximately 75% of the biparietal diameter. Combinations of different types of osmotic dilator are typically used.

In 1995 McMahon presented a 13-year personal series of 1362 intact D & E cases. Ninety-eight percent of these cases were performed at a licensed ambulatory surgical center. Only cases with serious fetal (n = 451) or maternal (n = 173) indications were done after 24-26 weeks' gestation. McMahon devised and refined exacting protocols for vertex and breech delivery to minimize the danger of cervical and uterine injury.

McMahon effected delivery only after achieving ample cervical dilation, and he used a minimum of instrument passes. For example, in vertex position, once the central nervous system (CNS) contents were evacuated using an auger-tipped trocar, he grasped the calvarium with forceps in a controlled manner and extracted the fetus. In breech presen-

tation, he converted the lie to footling and delivered the fetus using a Mauriceau-Smellie-Veit maneuver as described above. Dilation was sufficient to enable most complex presentations to be converted digitally or with a version forceps to vertex or breech presentation. McMahon devised special instruments for the procedure, and he recorded case-by-case measurements of fetal and cervical dimensions to improve delivery intervals, odds of intact delivery, and safety.

Using CDC criteria, four patients in McMahon's series experienced major complications, for a rate of 2.94 per 1000 cases. Three patients required transfusion, two for DIC and one for hemorrhage during dilation. The fourth patient required hospitalization for subacute bacterial endocarditis diagnosed 2 weeks after abortion. This major complication rate is virtually identical to that of an earlier series of nonintact D & Es reported by Hern (3.0/1000 cases) despite the fact that nearly one-fourth of the cases in McMahon's series exceeded Hern's 25-week gestation limit. In addition, Haskell has performed more than 1500 intact D & Es at 20-26 weeks' gestation without a serious event. No patient in his series experienced hemorrhage requiring transfusion, cervical laceration, uterine perforation, or retained tissue; and no hospitalizations or laparotomies were required.

(Ex. 70, at 136-37 (footnotes omitted).)

vi. ELCHLAL

Plaintiffs' Exhibit 110 is a peer-reviewed article authored by Uriel Elchlal, Inbar Ben Shachar, Dan Peleg, and Joseph G. Schenker entitled *Maternal Mortal-*

ity following Diagnostic 2nd-Trimester Amniocentesis, 19 Fetal Diagnosis & Therapy 195 (2004). The article recounted the death of two women, one 19 weeks pregnant and the other 21 weeks pregnant, after undergoing transabdominal amniocentesis for prenatal diagnosis of genetic disorders.

While acknowledging that amniocentesis is generally safe, after a review of the literature, the authors report "several cases of serious maternal complications, especially chorioamnionitis and septic shock." (Ex. 110, at 195 (footnote omitted).) The authors then present two new cases where women died undergoing this procedure in the second trimester. Among other things, the authors conclude that: "A full explanation prior to patient's consent is of importance, since maternal mortality, although rare, is a real danger even if the proper precautions are taken." (Ex. 110, at 198.)

According to Dr. Vibhakar, "the risk of an amniocentesis to remove fluid would be similar to performing [intraamniotic or intrafetal] . . . injections" of digoxin or KCl. (Tr. 348-50, Test. Dr. Vibhakar.)

vii. DREY

Defendant's Exhibit 560 is an article authored by Eleanor A. Drey, Lisa J. Thomas, Neal L. Benowitz, Nora Goldschlager, and Phillip D. Darney entitled *Safety of intra-amniotic digoxin administration before late second-trimester abortion by dilation and evacuation*, 182 Am. J. Obstet. & Gynecol. 1063 (2000). This article describes the use of digoxin to cause fetal death in abortions between 18 and 23 weeks when the termination was accomplished by D & E.

The authors describe their study this way:

More than 140,000 second-trimester abortions are performed annually in the United States, 94% of which are by dilation and evacuation. Second-trimester abortions account for a disproportionate burden of the morbidity and mortality related to abortion, with the risks of complications rising with each subsequent week of pregnancy. For example, the mortality risk associated with abortions performed at ≤8 weeks' gestation is 0.4 per 100,000 procedures, compared with a risk of 10.4 per 100,000 procedures associated with abortions performed at ≥21 week's gestation.

Clinicians have been using digoxin to facilitate second-trimester pregnancy termination for several years. Digoxin injection causes fetal death and is believed to make the dilation and evacuation procedure easier and safer because the fetal tissue is softened. Another advantage is that both the patient and the clinician may prefer to abort a dead fetus. Digoxin has been administered by the intracardiac, intrathoracic, intrafetal, and intra-amniotic routes, with doses varying from 0.25 to 2 mg. Most clinicians who use digoxin usually inject it 1 to 2 days before the dilation and evacuation procedure, at the time of laminaria placement.

Although there are no reports of maternal side effects or complications as a result of this use of digoxin, neither are there any evaluations of digoxin's safety or efficacy before dilation and evacuation. The purpose of this study was to assess the safety of intra-amniotic administration of digoxin before late second-trimester dilation and evacuation by evaluating its systemic absorption and its effects on car-

diac rhythm and conduction and on coagulation measurements.

(Ex. 560, at 1063 (footnotes omitted).)

The authors acknowledge that certain women were not considered appropriate subjects for use of injections. Those women were excluded

> because of significant medical illness or cardiovascular disease, current use of cardiac or antihypertensive medications, a known digoxin allergy, pregnancy complications (oligohydramnios, polyhydramnios, multiple gestation, or congenital anomalies), maternal weight 30% above ideal, difficult maternal venous access, or abnormal serum potassium levels (<3.5 mmol/1. or >5 mmol/1.).

(Ex. 560, at 1064.)

The authors conclude:

> We conclude that intra-amniotic administration of 1 mg digoxin before termination of pregnancy during the late second trimester does not result in clinically significant elevation of maternal serum digoxin levels, is not associated with evidence of digoxin toxicity, does not alter maternal cardiac rate or rhythm, and does not change clotting parameters. Although digoxin injection appears safe, determination of its clinical efficacy requires a randomized trial.

(Ex. 560, at 1066.)

viii. SHULMAN

Defendant's Exhibit 624 is an article written by Lee P. Shulman and Sherman Elias entitled *Second-Trimester Pregnancy Termination by Dilation and Evacuation After Detection of Fetal Abnormalities*, 1 J.

Women's Health 255 (1992). The article concludes that since D & E is superior to labor induction "with respect to morbidity, mortality" and other factors, the procedure should be used between 14 and 22 weeks of gestation to terminate pregnancy in the case of fetal abnormality. (Ex. 624, at 255.)

In 99% of the cases where the D & E was used, "[c]ytogenetic analysis" was successful. (Ex. 624, at 257.) In other words, the fetal parts dismembered during a D & E could be tested to determine the nature and extent of the abnormality. However, the authors acknowledge that "[p]athological examination of an intact fetus may be required in rare instances." (Ex. 624, at 257.) The authors conclude that "D and E by experienced obstetrician-gynecologists is the procedure of choice for most patients who elect to terminate pregnancies because of fetal abnormalities at or before the 22nd gestational week." (Ex. 624, at 257.)

ix. ABORTION SURVEILLANCE STATISTICS

Plaintiffs' Exhibit 32 contains United States Abortion Surveillance statistics for 2000 issued by the Department of Health and Human Services Centers for Disease Control and Prevention. Centers for Disease Control & Prevention, *Morbidity and Mortality Weekly Report: Abortion Surveillance-United States, 2000*, Vol. 52, No. SS-12 (Nov. 28, 2003). The statistics show that "[a]bortion ratios were highest for the youngest women (708 abortions per 1,000 live births for women aged <15 years)" and "[a]bortion trends by age indicate that since 1973, abortion ratios for women aged <15 years have been higher than for any other age group." (Ex. 32, at 4.) Further, the percentage of women who obtained "late" abortions-defined as at or after 16 weeks of ges-

tation-was greatest in women under 15 years of age. (Ex. 32, at 13 (Figure 4).)

The data also provide information on types of abortion procedure used:

> The percentage of abortions known to be performed by curettage (which includes dilatation and evacuation [D & E]) increased from 88% in 1973 to 98% in 2000, while the percentage of abortions performed by intrauterine instillation declined sharply, from 10% to 0.4%. The increase in use of D & E is likely due to the lower risk for complications associated with the procedure . . . . The percentage of abortions performed by D & E (curettage) at 13 weeks' gestation increased from 31% in 1974 (the first year for which these data were available) to 96% in 2000; the percentage of abortions performed by intrauterine instillation at 13 weeks' gestation decreased from 57% to 1.7%.

(Ex. 32, at 7 (internal references to tables omitted).)

x. STUDIES REFERENCED BY DR. FREDERIKSEN

Dr. Frederiksen identified several pieces of medical literature which she believes suggest that the D & E is safer than the second-trimester medical-induction abortion:

* A March 2004 Obstetrics and Gynecology publication entitled "Risk Factors for Legal Induced Abortion Related Mortality in the United States" was a descriptive epidemiological study of women dying of complications of abortion performed at all gestational ages. The article stated that D & E was two and one-half times safer than second-trimester instillation-induction ter-

minations. (Ex. 123, Test. Dr. Frederiksen 1051 & 1172-73.) Dr. Frederiksen testified that the study states the risk factor most strongly associated with mortality from legal abortion is gestational age. (Ex. 123, Test. Dr. Frederiksen 1173.) She acknowledges, however, that the study includes inductions performed with saline and prostaglandin instillations, a procedure which has declined in use since the 1970s due to its higher risk. (Ex. 123, Test. Dr. Frederiksen 1173-74.)

* The series of publications by David Grimes supports the safety of D & E procedures to about 20 weeks. Thereafter, the safety of the D & E depends on the physician performing the procedure. (Ex. 123, Test. Dr. Frederiksen 1052.)

* Chapman published a paper in the American Journal of Obstetrics and Gynecology that showed a 2.3 times higher risk of uterine rupture and hemorrhage in second-trimester induction abortions for patients who had a prior cesarean section. (Ex. 123, Test. Dr. Frederiksen 1052.) The Chapman article was based on a retrospective review of patient records from the University of Alabama hospital from 1980 through 1995. (Ex. 123, Test. Dr. Frederiksen 1171-72.)

* As a follow-up to the Chapman paper, Northwestern University performed a five-year study under IRB guidance to review the relative risks of D & E (including intact D & E) and medical-induction abortion procedures. The study did not reflect that medical inductions were associated with an increased risk of uterine rupture

and bleeding for patients with a history of prior cesarean section. According to Dr. Frederiksen, the study did show that "the induction method was significantly more risky for a patient and that D & E was significantly . . . safer." (Ex. 123, Test. Dr. Frederiksen 1052-53.) However, while an abstract of this study was published, the submitted paper was returned for revision. It has never been revised or published. The study was based on a D & E group with 561 patients compared to 85 induction-abortion patients, and the inductions were performed with medications that are not used today. (Ex. 123, Test. Dr. Frederiksen 1168-69 & 1171.)

* Phillip G. Stubblefield, *First and Second Trimester Abortion* 1046, *in Gynecologic, Obstetric, and Related Surgery* (David H. Nichols & Daniel L. Clarke-Pearson eds., 2000), states, "Early in [mid] trimester D & E is the safest method. Labor induction methods and D & E are comparable in the later midtrimester and both are much safer than hysterotomy or hysterectomy for abortion." (Ex. 123, Test. Dr. Frederiksen 1175-76; *see also* Exs. 65 & 628, at 1046.)

Dr. Frederiksen testified that although no specific study exists comparing intact D & Es and classical D & Es, the D & E data over the last 10 to 15 years indicates that physicians have moved from doing strictly dismemberment procedures to intact D & Es and the D & E has become safer over this time period. (Ex. 123, Test. Dr. Frederiksen 1054 & 1208.)

xi. STUDIES REFERENCED BY DR. CREININ

Dr. Creinin cited several studies regarding cervical incompetence following abortion procedures:

* The Kalish article (Exs. 55 & 596) entitled "Impact of Mid-trimester Dilation and Evacuation on Subsequent Pregnancy Outcome" is a retrospective chart review of D & E procedures performed at 14 to 24 weeks of gestation on 600 women. Ninety-six of these women had subsequent pregnancies. Ten of the women with subsequent pregnancies had deliveries before 37 weeks of gestation, with 5 having maternal and obstetrical reasons for early delivery. Of the remaining 5, 4 had cervical incompetence that pre-dated their prior D & E, and 1 had DES exposure which prompted her doctor to perform a cervical cerclage. None of the patients who delivered early had cervical incompetence related to the osmotic dilation involved in D & E surgery. The study is small but consistent with the theoretical understanding of what is physiologically expected. (Ex. 122, Test. Dr. Creinin 693-94.) The study did not include information on women who delivered babies at different institutions or who experienced first-trimester miscarriages. (Ex. 122, Test. Dr. Creinin 753-54.)

* The Schneider article (Exs. 73 & 621) entitled "Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation" was a case series of 171 women who had D & Es at 18 to 22 weeks of gestation. At the time of the report, 61 of the women had become pregnant after the D & E. None experienced cervical incompetence. (Ex. 122, Test. Dr.

Creinin 701-02.) The article states: "Dilation and evacuation for late second trimester termination seems to be safe. Intra- and postoperative complications are negligible." The study did not evaluate the intact D & E procedure and the average dilation was 2.9 centimeters +/- .9 centimeters. (Ex. 122, Test. Dr. Creinin 759-60.)

* The Henriet article (Exs. 49 & 585) entitled "Impact of induced abortions on subsequent pregnancy outcome: the 1996 French national perinatal survey" was a study of all births in France over a series of days with a study population of 12,432 women. The study concluded that induced abortion results in cervical incompetence. Dr. Creinin believes this "is an awful study" that cannot be relied on for any real conclusions related to second-trimester abortions because it is a retrospective study (with recall bias—the likelihood of receiving affirmative responses to leading questions about past events to explain a current bad outcome), and only four percent of the participants had a prior second-trimester abortion. (Ex. 122, Test. Dr. Creinin 754-56 & 780-83.)

* The Zhou article (Exs. 78 & 639) states: "[w]e have previously studied long-term consequences of an induced abortion in a subsequent pregnancy and found a slightly increased risk of low birth weight and pre-term birth, as well as placenta complications." (Ex. 122, Test. Dr. Creinin 757-58.) However, preterm birth is not the same as cervical incompetence. The majority of preterm births are caused by preterm labor and not

cervical incompetence. (Ex. 122, Test. Dr. Creinin 783-84.)

* The Autry article (Exs. 19 & 545) entitled "A comparison of medical induction and dilation and evacuation for second trimester abortion," published in 2002, compared labor induction and D & E procedures done between 14 and 24 weeks of gestation. Approximately 75% of the women had misoprostol inductions. According to Dr. Creinin, the study reflects that D & E is safer than labor induction, but it is a retrospective study and cannot be interpreted as a conclusive determination that D & E is safer. (Ex. 122, Test. Dr. Creinin 721-24.) The most common complication reported for labor induction was retained products of conception, but the article does not indicate how long the operators waited before performing a D & C. Moreover, a D & E virtually always requires surgical removal of the placenta by suction curettage. (Ex. 122, Test. Dr. Creinin 776- 77.)

Dr. Creinin knows of no data indicating that the osmotic dilation of the D & E leads to cervical incompetence. (Ex. 122, Test. Dr. Creinin 702.) Further, Dr. Creinin knows of no studies which consider whether the intact D & E procedure leads to a higher rate of cervical incompetence or preterm labor. (Ex. 122, Test. Dr. Creinin 758.)

xii. STUDIES REFERENCED BY DR. PAUL

Dr. Paul testified that from 1971 through 1979, a Joint Program for the Study of Abortion ("JPSA") was conducted by the Centers for Disease Control ("CDC"). JPSA was a prospective study that involved numerous

hospitals and clinics throughout the United States. Reports to the CDC were made by people trained to follow up on women who had abortions to determine if complications arose. The study included approximately a quarter of a million reports. Dr. Willard Cate and Dr. David Grimes were the co-directors of the JPSA study. (Ex. 125, Test. Dr. Paul 25-26.)

The Binkin article (Ex. 20)[97] entitled "Trends in Induced Legal Abortion Morbidity and Mortality" summarizes the conclusions of the 1971 through 1979 JPSA study conducted by the CDC under the direction of Dr. Cates and Dr. Grimes. The JPSA monitored 15 types of major complications, but most of the reported complications fell into the categories of sustained fever for three or more days, hemorrhage requiring transfusion, and unintended major surgery (e.g., abdominal or hysterectomy). Retained placenta was reported as a complication, but not a major complication. Based on the JPSA data, for first-trimester D & Cs, the rate of major complications was 0.2 to 0.6%; for saline and prostaglandin instillation inductions from 13 to 17 weeks of gestation, the rate of complications ranged from 1.7 to 3.0%; and for D & Es performed from 13 to 17 weeks of gestation, the rate of complications ranged from 0.6 to 0.9%. (Ex. 125, Test. Dr. Paul 26-30; *see also* Ex. 20, at 92, tbl. 7.) Although the medications and methods of induction abortion and of cervical dilation in D & Es have both changed since the 1970s, Dr. Paul believes the JPSA remains relevant in assessing the current safety of abortion procedures because it established the foundation for abortion safety and is the largest data set col-

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[97] This article was not received into evidence in total, but certain portions were projected on a screen and testified about at trial.

lected on the issue. The JPSA no longer exists because its purpose, determining if abortion is safe, has been served. (Ex. 125, Test. Dr. Paul 30-32.)

In the Binkin article, D & Es were compared to inductions that did not involve the use of prostaglandins or oxytocin to induce labor. (Ex. 125, Test. Dr. Paul 112-13.) The Binkin article reflects higher morbidity and mortality rates for second-trimester induction abortion than for D & E. (Ex. 125, Test. Dr. Paul 82-83.)

The Lawson article (Ex. 58)[38] entitled "Abortion mortality, United States, 1972 through 1987" is based on mortality data from 10 different sources, including vital records, death certificates, medical examiner reports, health care providers, and media reports. According to Dr. Paul, the article and its data reflect: (a) the rate of abortion-related death is very low; (b) the rate of abortion-related death increases with gestational age; (c) with legalization of abortion, the risk of death from abortion decreased 90% from 1972 until 1987; and (d) there is no association between the age of the woman and her risk of abortion-related death. (Ex. 125, Test. Dr. Paul 34-37.)

Dr. Paul testified that for second-trimester abortions performed before 16 weeks of gestation, the Lawson article reflects higher mortality rates for induction abortion than for D & E. After 16 weeks of gestation, the rate is approximately equal. The mortality rates for hysterotomy and hysterectomy are much higher than the rate of abortion-related death by D & E or induction. (Ex. 125, Test. Dr. Paul 84-85.)

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[38] This article was written by CDC investigators interpreting CDC data. It was received into evidence over the government's hearsay objection.

Dr. Paul described the Autry article (Exs. 19 & 545) entitled "A comparison of medical induction and dilation and evacuation for second trimester abortion," published in 2002, as a retrospective cohort study that compared labor induction and D & E procedures. There was a higher rate of complications with labor induction than with D & E, mostly due to retained placenta in the induction procedures. (Ex. 125, Test. Dr. Paul 85-86.) Dr. Paul opined that selection bias exists in the Autry study due to the lack of randomization and a difference in gestational age between the induction and D & E groups. However, the study includes a multiple regression analysis in an attempt to account for that bias. (Ex. 125, Test. Dr. Paul 114-15.)

Dr. Paul also pointed out that there are single-institution reports confirming that induction and D & E are both safe procedures, but that retained placenta occurs with inductions. (Ex. 125, Test. Dr. Paul 88-89.)

xiii. STUDIES REFERENCED BY DR. HAMMOND

Dr. Hammond testified that there are no medical studies supporting a finding that cervical dilation to perform a D & E, including an intact D & E, increases the risk of cervical incompetence. The Schneider and Caspi article (Ex. 73 and 621) entitled "Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation" found no evidence of subsequent obstetrical problems related to the cervical dilation performed for D & E surgery. (Ex. 124, Test. Dr. Hammond 596-97 & 684-86.) According to Dr. Hammond, for abortions between 20 and 24 weeks of gestation, there is some medical literature indicating that the D & E is safer and other medical literature indicating that labor induction is safer. (Ex. 124, Test. Dr. Hammond 690.) Dr. Hammond noted that most of the medical literature discussing retained

placenta following medical induction is from the 1980s and before the use of misoprostol. (Ex. 124, Test. Dr. Hammond 689-90.)

d. EXISTENCE OF MEDICAL DEBATE REGARDING SAFETY AND NECESSITY OF ABORTION PROCEDURES

i. GENERALLY

This case involves "an extraordinarily complex and delicate matter. I don't think that there really is any other topic in obstetrics, certainly, that is as controversial or as polarizing, as I have detected from my colleagues over the last month, than this particular topic." (Tr. 1646, Test. Dr. Lockwood (responding to why witness agreed to be an expert for the government in this case).)

Dr. Shadigian co-authored an article that systematically[99] studied available peer-reviewed abortion literature and attempted to assess potential long-term complications of abortion procedures. (Ex. 631 & Tr. 1562.[100]) The article stated that the long-term health consequences of elective abortion have become "highly politicized"—that is, people on "both sides" fear that their personal opinions about abortion will influence

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[99] Dr. Shadigian's study used inclusion and exclusion criteria to look only at bigger studies, not anecdotal case reports; studies having at least 100 subjects; and studies requiring its subjects to have a follow-up of two months or longer after an elective abortion. (Tr. 1536, Test. Dr. Shadigian.)

[100] This exhibit was received "[n]ot to prove that these articles are true or not true, but one, to prove or disprove the existence of a substantial body of medical opinion or to prove or disprove questions related to the Congressional effort to ascertain the true facts." (Tr. 1626.) However, there was no objection to the portions of the article which were read into the record by Dr. Shadigian.

what their research shows. "[I]nstead of people on both sides of this argument saying women's health is really important and we are both for healthy women and we need to . . . make some kind of collaborative effort to study long-term effects, it has been polarized instead." (Tr. 1535-39, Test. Dr. Shadigian.) As stated in Dr. Shadigian's article:

> Those who would grant a moral status to an embryo or fetus, and thus limit elective abortion, often use adverse health consequence claims as a tool to further their moral agenda while those who support no restriction on abortion access are, at times, unwilling to consider that pregnancy interruption could affect future and mental and physical health.

(Tr. 1540, Test. Dr. Shadigian.)

Appendix IV to this Memorandum and Order lists a myriad of journal articles, papers, CDC data, statements, press releases, letters, and newspaper editorials which were received by this court during the course of trial. As stated previously, these items were received not to prove that the assertions stated therein are true or not true, but to prove or disprove the existence of a substantial body of medical opinion or to prove or disprove questions related to the congressional effort to ascertain the true facts. (Tr. 1626.)

ii. MEDICAL ETHICS

The AMA committee on partial-birth abortion on which Dr. Sprang served did not reach a consensus regarding the medical ethics of the intact D & E procedure. (Tr. 1241-43, Test. Dr. Sprang; Ex. 13.)

iii. MEDICAL NECESSITY

Defense witness Dr. Bowes testified that there is "no consensus in the medical community that an intact D & X is never medically necessary." (Tr. 963, Test. Dr. Bowes.)

iv. SAFETY

Dr. Shadigan testified that it is possible that use of ripening agents such as laminaria and misoprostol may help reduce trauma to the cervix during abortion and reduce potential long-term risks of preterm birth in subsequent pregnancies. However, in her opinion, the issue needs to be studied because "there are no head-to-head studies looking just at how the cervix is dilated in a serial dilation [with laminaria] over several days versus how it's dilated over four hours [with misoprostol]." (Tr. 1553 & 1576-77, Test. Dr. Shadigian.)

Dr. Shadigian agrees that "cervical incompetence and compromised subsequent pregnancies are important but unresolved concerns related to second or third trimester abortions. Little research exists on whether those complications are more likely to result from D & E (or intact D & X) or from labor induction methods." (Tr. 1587, Test. Dr. Shadigian.)

Dr. Lockwood is "not an advocate" of the Partial-Birth Abortion Ban Act of 2003, but he believes there "is no established scientific evidence demonstrating the D & X procedure is a safer procedure." He believes the intact D & E warrants further study in order to determine its long-term complications. (Tr. 1732, Test. Dr. Lockwood; *see also* Ex. 126, Test. Dr. Westhoff 902 (there is no peer-reviewed publication finding that intact D & E is less safe than dismemberment D & E).)

While defense witness Dr. Bowes is aware that Drs. Haskell and McMahon in 1992 and 1995, respectively, have compiled case series describing their personal experience with the intact D & E or D & X, Dr. Bowes is not aware of any published peer-reviewed studies in the medical literature evaluating the safety of an intact D & E as compared with a disarticulation or dismemberment D & E or as compared with induction abortions. In Dr. Bowes's opinion, the only conclusion that can be drawn from the results of Dr. Haskell and Dr. McMahon is that "two physicians were able to accomplish a substantial number of these procedures with, at least, their assertion that there were very few complications." (Tr. 922-25 & 939-40, Test. Dr. Bowes.)

Dr. Cook is not aware of any published comparison studies looking at short-term and long-term safety issues involved with the intact D & E procedure. Dr. Cook believes the papers presented by Drs. Haskell and McMahon presenting short-term complication rates associated with the procedure do not contain a "historically concurrent" comparison or control group with which to compare outcomes and do not include long-term follow-up on the patients. Dr. Cook testified that while the Haskell and McMahon reports may be an initial step to gathering medical evidence, investigation by an independent body or investigation with the oversight of a supervisory committee or peer review is necessary in order to draw any significant inferences regarding safety of a new proposed medical procedure. Such investigation could then be followed by a clinical trial. (Tr. 1342-46, Test. Dr. Cook.) In Dr. Cook's opinion, one introducing a new medical procedure with a purported low complication rate has the "onus . . . to show that those complications, even if low, are lower

than other existing techniques, or offer some real benefit over other existing techniques. (Tr. 1346, Test. Dr. Cook.)

Dr. Lockwood is not aware of any medical literature that provides evidence that the intact D & E offers any safety advantage over the traditional D & E or medical induction. (Tr. 1700, Test. Dr. Lockwood.) Dr. Paul knows of no data indicating whether the intact D & E might lead to higher rates of cervical incompetence, preterm birth, or any other long-term adverse consequence. (Ex. 125, Test. Dr. Paul 105-07.)

Defense witness Dr. Bowes is not aware of any study or other valid scientific evidence that establishes that the intact D & E is less safe than the traditional D & E or than an induction abortion, or that establishes that the intact D & E is more dangerous to a woman than any other abortion method. Because of inadequate study in this regard, Dr. Bowes disagrees with the Act's second Congressional Finding which states that "partial-birth abortion remains a disfavored procedure that is not only unnecessary to preserve the health of the mother but, in fact, poses serious risks to the long-term health of women and in some circumstances their lives." Dr. Bowes believes there is no valid scientific evidence that supports Congress's Finding that "[a] ban on the partial-birth abortion procedure will therefore advance the health interests of pregnant women seeking to terminate a pregnancy." In short, Dr. Bowes believes it has not been "proven" that the intact D & E would be dangerous to women. (Tr. 953-57 & 994, Test. Dr. Bowes; Partial-Birth Abortion Ban Act of 2003, 18 U.S.C.A. § 1531, Cong. Findings (2) & (14(F)).) Dr. Bowes did not communicate his views with regard to these Congressional Findings to House or Senate

members prior to enactment of the Partial-Birth Abortion Ban Act of 2003. (Tr. 993, Test. Dr. Bowes.)

Dr. Lockwood agrees with "very little" of Congressional Finding (14)(A) of the Partial-Birth Abortion Ban Act of 2003, which describes purported "serious risks to the health of a woman" who has a "partial-birth abortion." For example, amniotic fluid embolism, categorized by Congress as a risk of the banned procedure, occurs in 1 of 5,000 deliveries and has an approximate 40% mortality rate. While surgical abortions might be more likely than nonsurgical abortions to uncover maternal blood vessels in the uterus that would allow amniotic fluid to enter into the uterine cavity, Dr. Lockwood "would be a little more suspicious about D & Es where there might be an increased risk of trauma than intact D & Xs where there might be a slightly reduced risk." Another risk mentioned in paragraph (14)(A) of the Congressional Findings, conversion of the fetus to a footling breech, could create a serious risk to the mother's health if it caused uterine perforation, but "there is some risk to all medical and surgical abortions."[101] (Tr. 1724-26, Test. Dr. Lockwood.)

According to Dr. Broekhuizen, although Congress concluded that converting a fetus to a breech position increases the risk of uterine rupture, abruption, amniotic fluid embolus, and trauma to the uterus, this finding is incorrect. Obstetrical literature may support this statement in the context of postviability fetuses, but it has no application to second-trimester pregnancy ter-

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[101] Dr. Lockwood admits that the documented and published risks of internal podalic version relate to periods of time closer to term when the uterine wall is thinner. (Tr. 1751, Test. Dr. Lockwood.)

minations or inductions up to 24 weeks. Dr. Broekhuizen testified that there are no known complications associated with breech conversion of the fetus during the second trimester. (Ex. 120, Test. Dr. Broekhuizen 517-18, 628-31.)

Dr. Creinin testified that Congress was incorrect in finding that converting the fetus to a breech presentation increases the risk of uterine rupture, abruption, and amniotic fluid embolus. (Ex. 122, Test. Dr. Creinin 669-70.) Specifically, Dr. Creinin made the following observations:

* Abruption is premature separation of the placenta from the uterus. Where a live birth is the goal, this is a severe complication because separating the placenta from the uterus eliminates the supply of oxygen to the fetus. Abruption is not, however, a risk or complication of a D & E because a live birth is not contemplated, and removing the placenta is an innate part and goal of the D & E procedure. (Ex. 122, Test. Dr. Creinin 670-71.)

* Amniotic fluid embolus occurs when amniotic fluid enters the woman's circulation, usually through a sinus (a large opening in the uterine lining which provides access for blood to reach the placenta). The embolus travels to the heart and lungs, causing respiratory and cardiac arrest. This complication of pregnancy or delivery is extremely rare and it would be very hard to show any increased risk at second-trimester gestational ages. More importantly, in a D & E, the amniotic fluid is removed at the outset of the procedure. (Ex. 122, Test. Dr. Creinin 673-75.)

* The act of abortion, whether done by labor induction or D & E, increases the risk of uterine rupture, but grasping a lower limb of the fetus and converting it to a breech presentation does not increase that risk. (Ex. 122, Test. Dr. Creinin 676-77.)

* Congress relied on a textbook statement that breech conversion is inappropriate, but this statement is inapplicable to the D & E procedure. The text cited was discussing delivery at term. (Ex. 122, Test. Dr. Creinin 677-78.)

Further, Dr. Creinin believes that Congress was incorrect in finding that dilating the cervix to perform an intact D & E increases the risk of cervical incompetence. Dr. Creinin maintains that there is no physiological basis for this conclusion and no medical studies that support that finding. (Ex. 122, Test. Dr. Creinin 691-92.)

Dr. Sprang is not aware of any published studies comparing the safety and risk of the intact D & E with the traditional D & E involving dismemberment of the fetus. He is also unaware of studies analyzing whether four-hour induction abortions, second-trimester laminaria dilation, or combined use of laminaria with misoprostol cause cervical incompetence. (Tr. 1157 & 1184, Test. Dr. Sprang.)

Dr. Cook admits that data "comparing contemporary induction methods versus other methods" between 16 and 20 weeks of gestation is "lacking" and there is not a "significant body of medical opinion that holds that induction abortion is sometimes the safest for a particular woman between 16 and 20 weeks of pregnancy." (Tr. 1398-99, Test. Dr. Cook.)

Dr. Shadigian believes "there is no basis to say the D & X is safer than any other procedure" because "the D & X has never been studied in a formal way in peer review literature." Specifically, "there is no sound basis on which to conclude the D & X is safer than medical induction." (Tr. 1513, Test. Dr. Shadigian.) However, Dr. Shadigian believes that medical induction is a safer abortion procedure than the intact D & E, even though there are no published peer-reviewed medical studies evaluating the intact D & E procedure. (Tr. 1570, Test. Dr. Shadigian.) Dr. Shadigian admits that her opinion that induction is safer than intact D & E for abortions at 20 weeks and later is "a hypothesis [she has] developed from looking at studies that don't look at D & X but look at other aspects of abortion procedure." (Tr. 1589, Test. Dr. Shadigian.)

Dr. Shadigan testified that because the D & E and intact D & E are separate procedures involving different gestational ages and amounts of dilation, safety data regarding the D & E cannot be used to demonstrate the safety of the intact D & E procedure. While the procedures share similarities, each procedure "has a different set of ways of going about delivering the infant." Similarly, safety data comparing the traditional D & E to old methods of induction cannot be applied to analyze the safety of the intact D & E as compared to modern medical induction. (Tr. 1554-55, Test. Dr. Shadigian.)

Dr. Shadigian believes there "is a substantial body of medical opinion that induction is safer than D & E after 20 weeks," but some physicians believe that the D & E is safer than induction after 20 weeks. (Tr. 1562, Test. Dr. Shadigian.)

Based on her review of relevant medical literature, Dr. Shadigian does not believe there "is a substantial body of medical opinion that D & X may be the safest and most appropriate procedure for some women in some circumstances." However, there may be "a substantial body of personal opinion [personal medical anecdotal evidence] that D & X may be the safest procedure for some women in some circumstances." (Tr. 1582, Test. Dr. Shadigian.)

Dr. Shadigian agrees that:

> Abortion-related morbidity is lower for D & E procedures than for labor-induction methods used in second-trimester abortions. However, the rates are similar for procedures performed at 20 weeks gestation and beyond. More research on complications and complication rates associated with various procedures and by gestational age is needed before firm conclusions about the relative safety of proceures can be drawn.

(Tr. 1593, Test. Dr. Shadigian (quoting from Ex. 41, Janet E. Gans Epner, et al., *Lateterm Abortion* 280 JAMA 724, 727-28 (1998)).)

An ACOG Statement of Policy provides in part:

> A select panel convened by ACOG could identify no circumstances under which [the intact D & X], as defined above, would be the only option to save the life or preserve the health of the woman. An intact D & X, however, may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman, and only the doctor, in consultation with the patient, based upon the woman's particular circumstances

> can make this decision. The potential exists that legislation prohibiting specific medical practices, such as intact D & X, may outlaw techniques that are critical to the lives and health of American women. The intervention of legislative bodies into medical decision making is inappropriate, ill advised, and dangerous.

(Ex. 5, at 3.)

Dr. Lockwood believes there is "a significant body of medical opinion that in some circumstances for some women, an intact D & E may be safer than the available abortion options." (Tr. 1752, Test. Dr. Lockwood.) However, if the intact D & E is the "preferred route" in any given case, "there are ways in which the practitioner can avoid violating the Act and still carry out the procedure." For example, "potassium chloride or Digoxin can be administered prior to the procedures." (Tr. 1769-71, Test. Dr. Lockwood.)

Based on the medical literature, Dr. Creinin believes that labor induction and D & E are equally safe, but the literature reflects a trend showing D & E as the safer procedure. The sample sizes of the studies are too low at this time to statistically confirm that perception. The relative safety of the procedures is primarily determined by considering the individual patient and whether, based on that patient's personal and medical circumstances, D & E is the preferred procedure. (Ex. 122, Test. Dr. Creinin 718-19.)

3. DEVELOPMENT OF SURGICAL TECHNIQUES

a. SURGICAL PROCEDURES GENERALLY

Dr. Mazariegas explained that when implementing a new surgical procedure, "there is a wide body of care and standard of care that we apply to our patients that

may include the clearly evidence-based therapies that are well[-]documented but may also include a large experience with alternative therapies that may be supported by other strong data or by therapies that are well[-]known but have not yet been subject to a formalized testing." (Tr. 807, Test. Dr. Mazariegos.)

According to Dr. Paul, evidence-based medicine means that if scientific information exists indicating that a particular method or procedure should be used, the doctor has a responsibility to use that method. Evidence-based medicine has, over the last two decades, become accepted in the medical community. (Ex. 125, Test. Dr. Paul 98-99.) Intuition per se is not used in the field of epidemiology. However, in the absence of scientific studies, doctors must use their best clinical judgment to render the safest care possible. (Ex. 125, Test. Dr. Paul 91 & 95-96.)

Dr. Mazariegos stated that surgeons and physicians are "beholden to the patient to provide the best therapy that is available," which means "to uphold the standard of care to apply to our particular patient in a particular medical condition as judged by the community in which we practice." Because this duty applies to the development of new procedures, "any development of a procedure that is outside the standard of care should then be expected to meet the minimal criteria of providing a safe approach, an effective approach, and one that has been . . . evaluated in some manner." Without prospective, comparative data, "it's impossible to objectively state that a procedure is better or safer" and "you would be likely to introduce [a] procedure that may not have a strong foundation or may be subject to bias." (Tr. 807-08 & 811, Test. Dr. Mazariegos.)

Different doctors develop different protocols, and a physician's skill and experience influence the safety of the procedure done. (Ex. 123, Test. Dr. Frederiksen 1233.)

Dr. Paul testified that randomized clinical trials are not required before medical techniques are used. (Ex. 125, Test. Dr. Paul 90.) For example, most of what is done in abortion practice has never been subjected to random clinical trials. (Ex. 125, Test. Dr. Paul 90-91.)

According to Dr. Clark, medical intuition or theory is not reliable in choosing safe medical treatment. For example, the rate of cesarean section dramatically increased when doctors believed that fetuses exhibiting certain heart rate patterns should be delivered rapidly to avoid cerebral palsy. However, though more cesarean sections were performed, the rate of cerebral palsy did not correspondingly decrease and the theory has now been proven wrong. Similarly, based on medical theory, DES, a synthetic estrogen, was once used to treat miscarriage, but it is now known to cause vaginal cancer and reproductive problems. (Ex. 891, Test. Dr. Clark 2389-90.)

Dr. Paul stated that ideally, surgical techniques should be subjected to comparison studies. Dr. Haskell's presentation regarding the intact D & E procedure occurred over 11 years ago, but no clinical trial of the procedure has occurred to date, and there are no "published" peer-reviewed studies considering the safety of the intact D & E.[102] (Ex. 125, Test. Dr. Paul 99 & 101-02.)

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[102] The wording "published" was added, presumably because of a motion in limine precluding the doctor from testifying about the then-unpublished Chasen study.

There are historical instances when the medical community's judgment on the safety of a procedure or method was proven wrong by subsequent randomized clinical studies. (Ex. 125, Test. Dr. Paul 103-05 (electronic fetal monitoring) & 108-09 (episiotomy).)

b. TEACHING OF SURGICAL PROCEDURES

Surgeons learn to perform surgical techniques in medical school and during their residency, and they update and expand their skills by reading relevant medical literature, consulting with colleagues on a day-to-day basis and at professional meetings, attending specific courses to learn how to perform various procedures, and arranging to work alongside a physician who performs a particular procedure. (Tr. 429-30, Test. Dr. Howell.) "[A] lot of education goes on informally. A lot of it [is] people . . . talking to each other. I talk to my colleagues all the time." (Tr. 434, Test. Dr. Howell.)

According to Dr. Howell, surgical procedures change and develop over time.

> The craft of surgery can change in a variety of different ways. Sometimes a brand new idea will come along and it will be adopted and picked up. That happens rather infrequently. Much more often, people, in the course of doing a procedure, will find that it is easier, safer, better in some way, to do it slightly differently than the way they had been doing it before. They'll adopt that method. If it seems to work, they'll talk to their . . . colleagues about it. They'll present it and, eventually, it may become accepted or it may not.

(Tr. 430-31, Test. Dr. Howell.) The physician shares his or her knowledge of the surgical procedure both informally—"in the hallway and the conference rooms"—and

formally at meetings. The information is then "eventually published in a peer review journal for people to read it and study." (Tr. 446, Test. Dr. Howell.)

For example, Dr. Howell noted that coronary artery bypass grafting, now an "absolutely standard" procedure, developed over many years of experimentation and accidental discoveries. For a century, it has been recognized that coronary disease or heart attacks are caused by the interruption of blood flow to some part of the heart, and that it would be helpful to improve blood flow to areas of the heart that do not get enough. "Whether you want to implant an artery or sew an artery in, or interpose a vein between the artery and the blocked area, or whether you want to stick a device up inside the artery and expand it to increase the blood flow, these are all different ways of accomplishing the same goal, which is to improve the blood flow." (Tr. 431-32, Test. Dr. Howell.)

Dr. Howell explained that one aspect of this bypass procedure came about in a "purely serendipitous fashion." While physicians attempted to inject dye into a patient's aorta, the catheter accidentally slipped into the coronary artery, something previously believed to be dangerous and probably fatal. While the doctors predicted that their mistake would kill the patient, it did not. "Instead, they saw that there was an obstruction there from the dye that had been injected. . . . [and then] came the knowledge that if we see the blockage, we can relieve it." Further development of the coronary artery bypass grafting procedure also resulted from physicians experimenting with interposing four different kinds of blood vessels and using different methods to sew the blood vessels together. (Tr. 432, Test. Dr. Howell.)

During his surgical residency, Dr. Carhart was taught to formulate surgical techniques that work for him, as long as the results are as good as, or better than, what is expected of other surgeons. "I have worked in thoracic surgery with many heart surgeons, and I have yet to see any two that do something the same way." (Tr. 625, Test. Dr. Carhart; *see also* Tr. 850, Test. Dr. Mazariegos (noting "[s]mall differences" in how surgeons perform liver-transplant surgery).)

According to Dr. Frederiksen, institutional review board approval is not required for changes in patient care or variations in a surgical technique used by an individual physician unless the change or technique is part of a medical study. (Ex. 123, Test. Dr. Frederiksen 1158-59.)

Dr. Broekhuizen does not classify the intact D & E as a new procedure. Rather, it is conceptually the same abortion method Dr. Broekhuizen has used since the 1970s in Africa and for his treatment of fetal anomalies in the 1980s, but now he has access to different instruments and medications. (Ex. 120, Test. Dr. Broekhuizen 584-88.)

According to Dr. Frederiksen, the D & E procedure has evolved since the 1970s in a manner consistent with how surgical techniques generally evolve. With the availability of laminaria and misoprostol, the use of serial laminaria, and changes in available instrumentation, more cervical dilation can be obtained and D & Es can be performed later in gestation with fetuses delivered more intact. The D & E performed by Dr. Frederiksen today is an extension of the D & E procedure she learned during her residency. Her method of performing D & Es is derived from discussions with other physicians and incorporates their suggestions when, in light

of her personal experience and skill, she believes a change in protocol may be beneficial. Studies can then be published to report a procedural variation and the safety and efficacy of that variation. (Ex. 123, Test. Dr. Frederiksen 1155-58 & 1230-31.)

Dr. Frederiksen believes that the Congressional Finding that intact D & E has "never been subject to even a minimal amount of normal medical practice development" is incorrect. Moreover, a ban on the intact D & E would affect the advancement of abortion practice by stopping the ability to explore the advantages of the intact D & E procedure. (Ex. 123, Test. Dr. Frederiksen 1159-60.)

c. INSTITUTIONAL D & X INSTRUCTION

Dr. Frederiksen opined that the Congressional Finding that there are no medical schools that teach the intact D & E procedure is incorrect. For approximately 10 years, Dr. Frederiksen has been teaching students to perform the D & E by removing the fetus as intact as possible. In her opinion, the Act would prohibit educating physicians on how to perform the safest second-trimester abortion procedure. (Ex. 123, Test. Dr. Frederiksen 1160-61.)

During Dr. Vibhakar's residency, a physician at a women's clinic taught her a procedure similar to that described by ACOG as the intact D & X, but the procedure was called a D & E. The physician taught her to do a "breech extraction up until the level of the calvarium, and then a puncture at the base of the skull, and then suction the cranial contents, and then extract the calvarium attached to the body." Dr. Vibhakar was taught during her residency that more dilation is preferable because it was safer-that is, it required "less ma-

nipulation within the uterus, so less risk of perforation, less chance of retained tissue, less chance of small fetal parts causing injuries such as cervical lacerations." (Tr. 343-44, Test. Dr. Vibhakar.)

Dr. Frederiksen's residency included rotating through the abortion service at Boston Hospital for Women where she received training in second-trimester D & Es and induction abortions. She has not had formal training since, but her procedures and methods have evolved based on communications with physicians and advances in equipment and medications. (Ex. 123, Test. Dr. Frederiksen 1044.)

Dr. Doe learned to perform what he or she calls the D & X procedure by reading articles authored by Dr. McMahon and Dr. Haskell, by talking with physicians from North America, by visiting clinics, and by applying personal experience. Dr. Doe currently teaches his or her D & X technique to medical students and OB/GYN residents at a university. (Tr. 65-66, Test. Dr. Doe.)

Dr. Hammond was formally trained to perform abortions to 20 weeks of gestation during his residency at the University of Rochester. With additional training from Dr. Frederiksen at Northwestern University, he gradually advanced the gestational age of his abortion practice to 24 weeks in approximately 2001. (Ex. 124, Test. Dr. Hammond 528-29.)

Dr. Chasen teaches medical residents how to perform D & C, dismemberment D & E, and intact D & E procedures at the New York Weill/Cornell Medical Center. (Ex. 121, Test. Dr. Chasen 1556- 57.)

Dr. Lockwood is not aware that the D & X procedure is currently being performed at Yale University,

but if the court proceedings challenging the Partial-Birth Abortion Ban Act of 2003 are successful and the Act is struck down, Dr. Lockwood would allow the procedure to be taught at Yale University. (Tr. 1667 & 1745-46, Test. Dr. Lockwood.)

Northwestern University teaches students how to perform second-trimester abortions by medical induction, D & E, and intact D & E. (Ex. 123, Test. Dr. Frederiksen 1046.) Specifically, Dr. Hammond teaches fourth-year residents and first- and second-year fellows to perform first- and second-trimester medical and surgical abortions, including D & E. To the extent that every D & E involves an attempt to remove the fetus as intact as possible, intact D & E is also taught. (Ex. 124, Test. Dr. Hammond 534-35.)

Dr. Paul teaches second-trimester D & E methods to students and physicians at Planned Parenthood Golden Gate. (Ex. 125, Test. Dr. Paul 10-16.)

Dr. Westhoff supervises and trains University of Columbia medical students in performing first-trimester D & Cs and second-trimester D & Es, including the intact D & E. The intact D & E method has been taught for the last five or six years as part of the fellowship program in family planning. (Ex. 126, Test. Dr. Westhoff 748-50 & 752-53.)

Dr. Westhoff is aware that the intact D & E is taught at the Albert Einstein College of Medicine, NYU, Cornell, Northwestern, and the University of California at San Francisco. (Ex. 126, Test. Dr. Westhoff 897-98.)

The intact D & E procedure is identified as an available method of second-trimester abortion in the medical text, *Williams Obstetrics*, which is regarded as an

authoritative text on obstetrics. (Ex. 121, Test. Dr. Chasen 1589.)

4. THE ACT'S EFFECT ON THE MEDICAL COMMUNITY

Dr. Carhart reads the Partial-Birth Abortion Ban Act of 2003 to encompass "every D & E" he does where fetal demise is not first induced because every abortion procedure involves "deliberately and intentionally vaginally" delivering a fetus and "performing . . . overt act[s]" that will cause the abortion. Specifically, the Act would affect Dr. Carhart's D & E procedures before 18 weeks, the point at which Dr. Carhart believes he can safely induce fetal demise before aborting the fetus. (Tr. 640-42, Test. Dr. Carhart.)

Dr. Fitzhugh reads the Act to apply to any gestational age and to the second-trimester procedures he performs, especially since he does not induce fetal demise prior to performing abortions. Dr. Fitzhugh questions the Act's terms "deliberately and intentionally" because those terms could describe any action he takes; the term "living fetus" because "living" can be measured by signs of life, existence of a heartbeat, cell reactions, or EEG activity; and the phrase "necessary to save the life of a mother" because while patient conditions like toxemia, unconsciousness, severe cardiac failure, and coma are clearly life-or-death situations, heavy bleeding, high fever, and infection are conditions that could be considered life-endangering to some, but only health-endangering to others. (Tr. 264-68 & 297, Test. Dr. Fitzhugh; Tr. 525-26, Test. Dr. Knorr (exception to save life of mother is vague because he would consider poorly controlled diabetes life-endangering, but others may not view it as life-threatening).)

Enforcement of the Act would limit Dr. Fitzhugh's ability to care for women, particularly when he performs 80% of the second-trimester abortions in central Virginia and finding a physician in that area to perform an induction procedure not prohibited by the Act would be difficult. (Tr. 269, Test. Dr. Fitzhugh.)

Dr. Knorr does not recognize the term "partial-birth abortion," as used in the Act, as a medical term. Dr. Knorr believes the Act may cover situations in which a portion of a breech fetus is outside the body of the mother and Dr. Knorr takes the "overt act" of removing a fetal limb, like an arm, that is above the umbilicus and is at the level of the vaginal opening. (Tr. 523-24, Test. Dr. Knorr.) He also believes the Act would cover "a majority" or a "large number" of D & Es he performs, including delivering the fetus intact to the head and reducing the size of the fetal skull; bringing out a part of a fetus in one pass and bringing out the remainder of the fetus in a second pass up to the fetal head; and treating miscarriages. (Tr. 524-25, Test. Dr. Knorr.)

Dr. Knorr is not willing to adjust his dilation procedure in order to avoid violating the Act because he believes that his dilation process is "safe and effective" and he believes that the fewer passes made inside the uterus, and the larger the parts removed, the safer the procedure for the patient. (Tr. 527, Test. Dr. Knorr.) Dr. Knorr does not view second-trimester induction abortions to be a reasonable alternative because it would be "taking a step backwards," and induction abortions are not readily available to women. (Tr. 527-28, Test. Dr. Knorr.)

In Dr. Vibhakar's opinion, the Act would cover the occasional D & Es she has performed where the fetus delivered to the level of the umbilicus, after which she

continued to perform the D & E and "commit overt acts that . . . could result in fetal death." The Act could also cover induction abortions Dr. Vibhakar supervises because:

> Sometimes in the case of an induction, a part of the fetus will deliver and part of the fetus will still be inside the uterus. And in trying to facilitate delivery of the rest of the fetus, the umbilical cord could become compressed, and that could cause fetal death or the fetus could become disarticulated, and that could cause fetal death.

Dr. Vibhakar characterizes the Act as "vague" because it does not specify whether the fetus must be intact up to the level of the umbilicus to be covered by the Act; whether the Act would apply when a portion of the fetus's trunk is removed from the patient early in the procedure, followed by actions that can result in fetal death; and what an "overt act" is. (Tr. 351-53, Test. Dr. Vibhakar.)

If the Act eventually goes into effect, Dr. Vibhakar may discontinue performing second-trimester terminations. (Tr. 353, Test. Dr. Vibhakar.)

Dr. Doe believes the Act would apply to cases like one he or she recently handled. A 16-week patient who had previously had several vaginal deliveries presented herself to Dr. Doe on an urgent basis. After only one day of administering four to five Dilapan and misoprostol on the morning of the procedure, the patient began contracting and was uncomfortable. When Dr. Doe examined the patient with a speculum, he or she observed bulging membranes. After Dr. Doe ruptured the membranes, the fetus prolapsed down and the head got stuck. Dr. Doe then grasped the fetal head with for-

ceps, compressed it, and removed the fetus. Because the fetus was only 16 weeks, Dr. Doe had not induced fetal demise prior to the procedure. Further, Dr. Doe "had no particular plan" as to whether he or she would remove the fetus intact or dismembered when he or she began the procedure, and he or she paid no particular attention to when fetal death actually occurred. "I have . . . seen fetal life even after the fetal head has been compressed." (Tr. 74-77, Test. Dr. Doe.)

Dr. Doe also believes the Act would cover those cases in which Dr. Doe achieves very generous, yet unpredicted, dilation and the fetus "just pops out when ~~[he or she]~~ rupture[s] the membrane," as well as to his or her D & X procedures in which he or she deliberately attempts to remove the fetus as intact as possible.

> I would never know if I was going to be breaching the [A]ct using the techniques that I currently use, because I don't know when the fetus dies. So I don't know when I can do something. And if the fetus was still to be showing some evidence of life when I performed an overt act, whatever that may be, then I would be in breach of the [A]ct. . . . I would be spending my time trying to determine if there was any evidence of fetal life before removing the fetus for no important medical reason.

(Tr. 77-78, Test. Dr. Doe.) Dr. Doe cannot recall a case in which he or she performed an abortion when the head of a living fetus protruded outside the woman's body at the outset of the procedure. (Tr. 124-25, Test. Dr. Doe.)

When the fetus is alive and passes through the cervix intact or substantially intact past the level of the fetal umbilicus and to the level of the calvarium, Dr.

Creinin collapses the fetal head to complete the D & E. He cannot predict at the outset that the fetus will pass through the cervix in this manner, but if it occurs and he responds by collapsing the fetal skull to complete the abortion, he believes the Act has been violated. (Ex. 122, Test. Dr. Creinin 678-81, 744-47, 786.)

Dr. Broekhuizen believes that the Partial-Birth Abortion Ban Act could ban some second-trimester abortions, techniques used to treat women undergoing a second-trimester miscarriage, and procedures that, based on medical judgment, are needed to respond to specific maternal health and fetal conditions or to obtain information for planning future pregnancies. (Ex. 120, Test. Dr. Broekhuizen 494-95.)

According to Dr. Broekhuizen, the Act could impact scenarios where dilation is sufficient in a typical D & E such that the fetus comes out intact, where serial laminaria are used for medical reasons to promote delivery of an intact fetus, and where labor induction is used. (Ex. 120, Test. Dr. Broekhuizen 551.) For example, misoprostol may, within four hours, lead to rapid labor and delivery of the fetus either completely or partially. This response cannot be reliably predicted, according to Dr. Broekhuizen. When partial delivery occurs, the fetus may be alive and outside the woman's body past the fetal umbilicus with the fetal head compressed against the internal cervical os. This circumstance necessitates compression or decompression of the fetal head, which results in fetal demise, to effect complete delivery of the fetus. (Ex. 120, Test. Dr. Broekhuizen 512-13.)

Dr. Broekhuizen described several examples of instances that may have been covered by the Act if it were effective at the time:

* Dr. Broekhuizen had a patient whose fetus was diagnosed with a lethal skeletal dysplasia.[103] The patient had previously had a cesarean section and very traumatic birthing process and was not willing to endure labor induction but wanted a pathological examination of the skeletal structure of the fetus. Serial laminaria were used to cause substantial dilation of the cervix. While the patient was able to deliver the fetus without necessitating crushing or suctioning of the fetal skull, an intact D & E may have been necessary. (Ex. 120, Test. Dr. Broekhuizen 539-40 & 599-601.)

* An abortion was performed on a fetus diagnosed with a lethal chromosomal anomaly and macrocephaly. The woman could not deliver the large fetal head. She could have undergone a cesarean section with a very large incision. Instead, labor was induced, the fetus was breech delivered and alive when the fetal head lodged in the cervical os. A trocar was used to collapse the skull to complete the delivery. (Ex. 120, Test. Dr. Broekhuizen 540-42 & 602-06.)

* An abortion was performed on a fetus with nonimmune hydrops or fetal ascites (fluid in the abdominal cavity). The fetal head delivered first, but the abdomen was too large to deliver, so a trocar or spinal needle was used to decompress

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[103] Skeletal dysplasia refers to over 120 types of disorders, "each of which results in numerous disturbances of the skeletal system and most of which include dwarfism." *Stedman's Medical Dictionary* 556 (27th ed. 2000).

the fetal chest and abdomen to deliver the baby. (Ex. 120, Test. Dr. Broekhuizen 552-53.)

Although Dr. Broekhuizen's practice is limited to abortions to preserve maternal health, the Act poses a risk to his practice. He questions the meaning of "life endangerment"; who decides a mother's life is being endangered; and what level of mortality risk is sufficient to be considered necessary to save the life of the mother. Dr. Broekhuizen stated that some women will accept a 30% risk of personal death to save the fetus, while others deem a 2% risk too high. He testified that this is a personal and family choice to be made with the doctor's assistance. The Act permits others to second-guess that patient's decision even though the abortion decision made was very necessary for that specific patient under those particular circumstances. (Ex. 120, Test. Dr. Broekhuizen 557-58.)

The Act's language providing for state medical board review provides little comfort to Dr. Broekhuizen. He believes the process starts with an indictment and proceeds to a determination made by those with no expertise in his area of practice re-evaluating decisions made in a specific situation encountered by a specific patient. Further, even if the doctor's decision is upheld, Dr. Broekhuizen believes that the medical review board process would significantly impact his practice and his ability to provide similar services to other patients. (Ex. 120, Test. Dr. Broekhuizen 560-61.)

Dr. Broekhuizen testified that if enforced, the Act will make it significantly more difficult for him to provide medically appropriate services to patients. One alternative would be to increase the use of lethal injection so the fetus is not alive at the time of the abortion, but this solution would in some circumstances under-

mine the best interests and personal choices of his patients. (Ex. 120, Test. Dr. Broekhuizen 563.)

Dr. Creinin opposes the Act primarily because he believes Congress should not legislate the abortion procedures physicians perform on previable fetuses and because the Act does not serve the best interests of women or their health care providers. (Ex. 122, Test. Dr. Creinin 732-33.)

Dr. Paul believes that first-trimester, hysterotomy, and hysterectomy abortion procedures are not affected by the Act, but the Act does affect D & E abortions and could affect labor-induction abortions. (Ex. 125, Test. Dr. Paul 49-50.) Dr. Paul testified that the Act's language describing delivery of "any part of the fetal trunk past the navel" and outside the woman's body could mean the fetal trunk past the navel is outside the cervix, or that the fetal trunk past the navel is outside the woman's body, or that a disarticulated fetal part above the navel is removed through the cervix. In each of these cases, the fetus may be living. (Ex. 125, Test. Dr. Paul 77-78.)

Dr. Paul stated that the Act does not leave the determination of when a partial-birth abortion is necessary to save the life of the mother to the treating physician and instead allows the physician to be second-guessed by others as to whether an intact D & E was sufficiently necessary. Moreover, Dr. Paul is unclear whether this language means an intact D & E is not necessary if the abortion can be completed by hysterotomy or hysterectomy, even though these procedures have a much higher morbidity and mortality rate. (Ex. 125, Test. Dr. Paul 81-82.)

Dr. Paul stated, "I don't feel like I can practice medicine well being second-guessed by a third party about what my purpose is in completing and in doing a certain act during an abortion when that person also has the power to put me in prison." (Ex. 125, Test. Dr. Paul 80.) She believes the Act would require her to decide whether to continue practicing medicine in the safest manner possible for women despite the risk of imprisonment, and whether to teach all methods of abortion practice, including the intact D & E, or at least to inform her students that they may risk imprisonment if they perform an intact D & E. (Ex. 125, Test. Dr. Paul 92-93.) She believes the Act will affect her relationship with patients who trust her to provide the best care possible, while permitting spouses and parents of minors to file a civil action against her for allegedly violating the Act when neither has the authority to stop the patient from obtaining an abortion. (Ex. 125, Test. Dr. Paul 93-94.)

According to Dr. Westhoff, the language of what is banned by the Act is written broader than Congress's Findings and could include D & Es that involve dismemberment. It is therefore very difficult in her opinion to determine precisely what medical procedures are banned. (Ex. 126, Test. Dr. Westhoff 845-46.) Dr. Westhoff believes the language of the Act bans her method of performing the D & E. She fears prosecution under the Act because when she performs D & Es, many of the fetuses present in a breech position; they are alive, vaginally delivered intact to the level of the umbilicus, and are killed in the procedure; and each step of the abortion is deliberately performed. (Ex. 126, Test. Dr. Westhoff 842-51.)

Dr. Westhoff testified that the same steps are used to perform a dismemberment D & E as an intact D & E with various outcomes that potentially violate the Act. (Ex. 126, Test. Dr. Westhoff 856-57.) For example:

* A D & E may begin as a dismemberment D & E, with one leg dismembered, but the fetus remains alive and is delivered intact and outside the woman's body to the level of the fetal umbilicus. (Ex. 126, Test. Dr. Westhoff 855.)

* The fetal trunk may be the first part grabbed, and while the fetus remains alive, that part may be pulled into the vaginal area and outside the woman's body. (Ex. 126, Test. Dr. Westhoff 855-56.)

Dr. Westhoff pointed out that one step of all dismemberment D & Es is delivering the fetus for the purpose of committing a lethal act. (Ex. 126, Test. Dr. Westhoff 856.) Further, labor induction involves vaginal delivery of a living fetus outside the woman's body, and cutting the umbilical cord is a lethal act. (Ex. 126, Test. Dr. Westhoff 857-59.)

Dr. Westhoff testified that of the 800,000 miscarriages (spontaneous abortions) that occur in the United States every year, 75% require medical intervention to complete emptying the uterus, a process that is necessary to preserve the woman's health and safety. This process may require the overt act of cutting the umbilical cord or collapsing the fetal skull after the fetus is delivered outside the woman's body to the level of the umbilicus. (Ex. 126, Test. Dr. Westhoff 859-62.)

In Dr. Westhoff's opinion, determining when a woman's life is in danger is a matter of judgment which

may be subject to a different interpretation by other physicians or prosecutors. (Ex. 126, Test. Dr. Westhoff 884.)

Dr. Westhoff offered several opinions regarding the Congressional Findings that are attached to the Partial-Birth Abortion Ban Act of 2003:

* Congress was incorrect in finding that dilating the cervix to perform an intact D & E increases the risk of cervical incompetence. There are no medical studies supporting that finding, and physiologically, dilation with osmotic dilators is substantially slower and less than what occurs during delivery at term. Cervical dilation with osmotic dilators does not cause cervical incompetence. (Ex. 126, Test. Dr. Westhoff 789-90 & 889.)

* Congress was incorrect in finding that the intact D & E increases the risk of uterine rupture, abruption, and amniotic fluid embolus. There is no published medical literature to support any of these findings. (Ex. 126, Test. Dr. Westhoff 889-90.)

* Congress was incorrect in finding that the conversion to a footling breech increases the risk of uterine injury. This statement is inconsistent with her practice and the practice of her group, and Dr. Westhoff knows of no medical literature to support this finding. The procedure is more difficult when the fetus is at term because the fetus is larger. (Ex. 126, Test. Dr. Westhoff 890-91.)

* Congress was incorrect in finding that blindly forcing a sharp instrument into the base of the fetal skull poses a risk to the mother of lacerations and secondary hemorrhaging. The procedure is not a blind procedure and neither she nor the colleagues in her group have ever had a complication related to collapsing the fetal skull. (Ex. 126, Test. Dr. Westhoff 891-92.)

* Assuming Congress's Findings regarding risk were valid, inducing fetal demise before beginning surgical removal does not reduce those risks. (Ex. 126, Test. Dr. Westhoff 892-93.)

* Congress was incorrect in finding that the intact D & E poses serious risks to the long-term health of women and a danger to their lives. There is no biological plausibility to this statement. (Ex. 126, Test. Dr. Westhoff 893-94.)

* Congress was incorrect in finding that the intact D & E is never necessary to preserve the health of the woman, poses a serious risk to the woman's health, and violates the medical standard of care. (Ex. 126, Test. Dr. Westhoff 894-96.)

* Congress was incorrect in finding that the intact D & E is not taught at medical teaching institutions. At the time the Act was written, Dr. Westhoff was teaching the procedure, and it was also being taught at the Albert Einstein College of Medicine, NYU, Cornell, Northwestern, and the University of California at San Francisco. (Ex. 126, Test. Dr. Westhoff 897-98.)

* Congress was incorrect in finding that banning the intact D & E advances women's health. The procedure reduces the risk of complications which advances women's health interests. (Ex. 126, Test. Dr. Westhoff 898.)

* Congress was incorrect in finding that the intact D & E confuses the medical, legal, and ethical duties of physicians to preserve and promote life because the physician acts directly against the physical life of the child when it delivers the fetus intact to the head and then kills it. The goal of abortion is to terminate the pregnancy and the fetus will not be alive at the end of the procedure. As with all abortions, the procedure is done at the patient's consent after the medical, legal, and ethical issues have been discussed. (Ex. 126, Test. Dr. Westhoff 899-900.)

* Congress was incorrect in finding that the intact D & E is not an accepted medical practice, and was incorrect in finding that it has never been subject to even a minimal amount of normal medical practice development. (Ex. 126, Test. Dr. Westhoff 901.)

Dr. Clark disagrees with most of Congress's Findings as set forth in section (14)(A) of the Act. With the exception of the risk of preterm birth now raised by the Chasen article, there is no medical evidence to support the risks identified by Congress. Aside from the risk of preterm birth, saying the intact D & E is less safe than the dismemberment D & E is pure speculation and has no place in scientific discussion. (Ex. 891, Test. Dr. Clark 2418-21.)

Within the context of safe medical procedures, Dr. Clark believes that doctors need some flexibility to perform procedures in a manner that accounts for their particular skills, experience, and the unanticipated events that occur in the course of a procedure. (Ex. 891, Test. Dr. Clark 2422-23.)

Dr. Hammond offered several observations about the Partial-Birth Abortion Ban Act of 2003 and its Congressional Findings:

* The language of what is banned by the Act is written more broadly than Congress's Findings in support of the Act. The language of the ban could include dismemberment D & Es and medical-induction abortions. It is therefore very difficult to determine precisely what medical procedures are banned. (Ex. 124, Test. Dr. Hammond 618, 621-22, 630-34.)

* The overt and lethal act of the ban itself is not limited to what is discussed in the Congressional Findings. Although Congress's Findings discuss a fetus with the head lodged in the uterus and the use of a scissors to decompress and suction the fetal head, the ban is not limited to such circumstances. For example, Dr. Hammond does not clearly understand if the Act would be violated if the fetus is delivered to the level of the navel, and the umbilical cord is cut, which is an overt lethal act, even if the skull has not been decompressed. (Ex. 124, Test. Dr. Hammond 624.) Further, in a breech presentation, the fetus may be delivered intact to the fetal navel, but the contents of the fetal abdomen have been pushed upward and are now distending the ab-

domen above the internal cervical os which precludes the fetus from passing through the cervix intact. In such cases, Dr. Hammond puts an incision in the fetal abdomen to cause decompression. This is a lethal act and although not discussed in Congress's Findings, may be banned by the Act. (Ex. 124, Test. Dr. Hammond 631-32.)

* Dr. Hammond testified that for every D & E, the doctor is deliberately and intentionally dilating the cervix to vaginally deliver a fetus. (Ex. 124, Test. Dr. Hammond 630.) Dr. Hammond questions whether many circumstances that arise during a dismemberment D & E, described below, violate the Act. For example, if the fetal abdomen is the first part grasped and pulled, a living fetus may be delivered outside the body of the woman past the fetal navel. The dismemberment thereafter will kill the fetus and may be a lethal act that is banned by the Act. (Ex. 124, Test. Dr. Hammond 630-31.) Also, if the doctor is able to grasp one lower extremity and remove the fetus past the level of the fetal navel, a dismemberment D & E will occur. The dismemberment itself is a lethal act that may violate the Act. (Ex. 124, Test. Dr. Hammond 632-33.)

* Dr. Hammond testified that for every labor-induction abortion, the doctor is deliberately and intentionally dilating the cervix to vaginally deliver a fetus. The labor induction may not be fully successful and the fetus may deliver until the head is lodged in the cervical os. This circumstance can occur and is not uncommon with

hydrocephalic fetuses. According to Dr. Hammond, the doctor can either: (1) collapse the fetal head, which violates the Act, or (2) continue to pull the fetus, causing it to tear at the neck. This is also a lethal act, but now the doctor must reach into the uterus with a forceps and try to grasp the fetal head to remove it. (Ex. 124, Test. Dr. Hammond 641-43.)

* Regarding the "living" fetus language in the Act, every D & E is an intentional and deliberate vaginal delivery of a living fetus, which to Dr. Hammond means a fetus with a heartbeat. (Ex. 124, Test. Dr. Hammond 626-27.)

* Dr. Hammond believes "outside the body of the mother" is ambiguous in the context of medicine. In the reality of an operating room, it is hard to tell when the fetus is outside the woman's body. It is unclear whether "outside the women's body" means outside the uterus, or beyond the vaginal opening. Even if it means beyond the vaginal opening, for some women, the relaxation caused by anesthesia or the use of the tenaculum causes the cervix to lower to the level of the vaginal opening, and sometimes this condition evolves during the course of the surgery. (Ex. 124, Test. Dr. Hammond 627-29.)

Dr. Hammond identified several of the Act's Congressional Findings that, in his opinion, are erroneous:

* Congress was incorrect in finding that dilating the cervix to perform an intact D & E increases the risk of cervical incompetence. There are no medical studies supporting that finding, and the Schneider and Caspi article (Exs. 73 & 621) enti-

tled "Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation" found no evidence of subsequent obstetrical problems related to the cervical dilation performed in preparation for D & E surgery. (Ex. 124, Test. Dr. Hammond 597 & 684-86.)

* Congress was incorrect in finding that the intact D & E increases the risk of uterine rupture, abruption, and amniotic fluid embolus. Dr. Hammond knows of no published medical literature to support any of these findings. The risk of uterine rupture is less with intact D & E, there is no difference in the rate of abruption, and since the amniotic fluid is absent at the outset of the D & E, amniotic fluid embolus is not a risk. (Ex. 124, Test. Dr. Hammond 598-99.)

* Congress was incorrect in finding that conversion of a fetus to a footling breech increases the risk of uterine injury. Dr. Hammond knows of no medical literature to support this finding in the context of second-trimester abortion. The uterus at that stage is much different than at term, with much more room for fetal movement. D & Es, whether dismemberment or intact, all require manipulation and movement of the fetus within the uterus, and have been done safely for 30 years. While the internal podalic version is more dangerous when the fetus is at term because the fetus is larger, that fact has nothing to do with a second-trimester abortion. (Ex. 124, Test. Dr. Hammond 600-03.)

* Congress was incorrect in finding that blindly forcing a sharp instrument into the base of the

fetal skull poses a risk to the mother of lacerations and secondary hemorrhaging. The procedure for decompressing the skull in an intact D & E is not a blind procedure; on the other hand, trapping and grasping the dismembered skull in a dismemberment D & E is a blind procedure. In an intact D & E, the fetal head is at the level of the cervical os and the doctor can see the placement of the scissors in nearly every case, and can in all cases feel where the scissors are with his or her finger to confirm that they are not in a position to injure the cervix or uterus. In contrast, if the fetal skull is dismembered, instruments must be used to feel the inside of the uterus while attempting to grasp the bobbing skull at the end of the forceps. (Ex. 124, Test. Dr. Hammond 604-06.)

* Congress was incorrect in finding that the intact D & E poses serious risks to the long-term health of women and a danger to their lives. There is a lower risk of medical complications associated with intact D & E. (Ex. 124, Test. Dr. Hammond 607-08.)

* Congress was incorrect in finding that the intact D & E is never necessary to preserve the health of the woman, poses a serious risk to the woman's health, and violates the medical standard of care. Since Dr. Hammond has been doing the procedure, or for the last 15 years, the standard of care has been to remove the fetus as intact as possible. (Ex. 124, Test. Dr. Hammond 608-09.)

* Congress was incorrect in finding that the intact D & E is not taught at medical teaching institutions. Northwestern has been teaching it since Dr. Hammond arrived there in 2001, and it is described in the *Clinician's Guide to Medical and Surgical Abortion*,[104] which is the textbook his residents and fellows use for training. (Ex. 124, Test. Dr. Hammond 610.)

* Congress was incorrect in finding that banning intact D & E advances women's health. A ban on intact D & E will place patients at risk by removing the safest abortion choice as an option. (Ex. 124, Test. Dr. Hammond 612.)

* Congress was incorrect in finding that the intact D & E confuses the medical, legal, and ethical duties of physicians to preserve and promote life because the doctor's patient is the woman, and the doctor is acting on the woman's behalf to perform the safest procedure under the circumstances. (Ex. 124, Test. Dr. Hammond 613.)

Dr. Howell noted that if the Act becomes effective, physicians could not study the intact D & E procedure and variations thereof. (Tr. 470, Test. Dr. Howell.)

5. GROUP STATEMENTS REGARDING ACT

a. ACOG

Dr. Joanna M. Cain was a member of the ACOG task force created in 1996 specifically to review late-term abortion procedures. She was designated as the 30(b)(6) ACOG representative for these legal proceed-

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[104] Edited by Dr. Paul, the textbook was "developed" by the National Abortion Federation. (Ex. 124, Test. Dr. Hammond 656.)

ings. (*See* Ex. 39 (30(b)(6) deposition notice) & Ex. 115, Test. Dr. Cain 216.)

Dr. Cain graduated from Creighton University Medical School and completed a residency in obstetrics and gynecology at the University of Washington. Her residency program included training on second-trimester abortion methods. She also completed a fellowship at the Memorial Sloan-Kettering Cancer Center in New York City where she was trained in the care of pregnant women with malignancies, including performing first- and second-trimester abortions related to those underlying health issues. Dr. Cain now chairs the department of obstetrics and gynecology at a university and serves as director of a women's health center. Dr. Cain does not currently personally perform abortions, but supervises physicians who perform D & E, induction, intact D & X (as defined by ACOG), hysterectomy, and hysterotomy abortion procedures. Dr. Cain has special certifications in biomedical ethics, obstetrics and gynecology, and gynecologic oncology. She specializes in gynecologic cancer treatment and biomedical ethics consulting. (Ex. 115, Test. Dr. Cain 13-18 & 22-30.)

Dr. Cain has never performed an elective abortion or an intact D & E. She has performed less than 25 D & Es over the course of her career, less than 5 induction abortions, 1 hysterotomy, and less than 10 hysterectomies. (Ex. 115, Test. Dr. Cain 19-22.)

i. ACOG GENERALLY

ACOG is a nonprofit organization dedicated to the ongoing education of its members, research, and advocacy on the topic of health care for women. It has 44,000 members from the United States, Canada, and Mexico. ACOG is organized into 12 regional districts

that report to the national organization. Each state is a subsection within an assigned district. The executive board consists of officers and representatives from each of the ACOG districts. Members of the executive board are elected by vote of the district membership. (Ex. 115, Test. Dr. Cain 222-26.)

The members of ACOG committees and task forces are ACOG fellows. To become an ACOG fellow, the doctor must first be certified by the American Board of Obstetrics and Gynecology and then must apply for and be accepted as an ACOG fellow. Over 90% of the physicians who are board-certified in obstetrics and gynecology are members of ACOG. (Ex. 115, Test. Dr. Cain 44-45 & 223-24.)

ii. THE INTACT D & X TASK FORCE

In 1996 and 1997, ACOG policy statements were developed through committees or task forces of experts in a particular area of medicine. These policy statements were then proposed to the ACOG executive board. Members of the board reviewed the proposed policy statements, made any appropriate editorial changes, and adopted the policy statements if they were deemed worthy. The ACOG executive board had the ability to change both the wording and substance of a proposed policy statement. A policy or guideline under consideration by an ACOG task force is not formally discussed with non-committee fellows of ACOG until it is accepted by the ACOG executive board. (Ex. 115, Test. Dr. Cain 40-41 & 45-46.)

Consistent with its standard business practice, AGOC created a task force in 1996 specifically to re-

view late-term abortion procuedures.[105] Dr. Cain was a member of the task force. (Ex. 115, Test. Dr. Cain 216.) Other than the task force and the ACOG executive board, there were no other ACOG committees or groups involved in developing the 1997 ACOG policy statement on intact D & E. (Ex. 115, Test. Dr. Cain 43-44 & 226-27.)

The process for developing the ACOG Statement on Intact Dilation and Extraction (Ex. 6) was consistent with the method used by ACOG in formulating other policy statements. The process began by carefully selecting task force members based on their expertise and viewpoint. These members were sent background materials for review. The members reviewed materials they were provided, reviewed other relevant sources of expertise in the area, and wrote and edited the policy as a committee. The proposed ACOG Statement on Intact Dilation and Extraction (Ex. 655) was then presented to the ACOG executive board by Dr. Fred Frigoletto, the president of ACOG at the time, and was discussed with the board members at that meeting.[106] The board members had access to the materials reviewed by the task force and, as leaders within ACOG, had a broad range of expertise. Editorial concerns were discussed, and the final document was produced with the agreement of the board members. (Ex. 115, Test. Dr. Cain 46-52.)

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[105] ACOG has standing practice-related committees, but does not have such a committee to deal specifically with the issue of abortion. (Ex. 115, Test. Dr. Cain 41-42.)

[106] Dr. Frigoletto was recovering from heart transplant surgery at the time of the ACOG 30(b)(6) deposition. (Ex. 115, Test. Dr. Cain 229.)

Dr. Frigoletto chose task force members from diverse backgrounds. Factors considered in choosing the members included geography, gender, race, viewpoint, and expertise. Dr. Cain's area of expertise for this project was medical ethics. (Ex. 115, Test. Dr. Cain 55-58.)

In addition to Dr. Cain, the task force members included:

* A practicing OB/GYN who is Catholic and not strongly affiliated with a university or academic practice. This physician opposed abortion and would not have overseen or performed the intact D & X, as defined by ACOG. (Ex. 115, Test. Dr. Cain 61-62, 70, 198.) This physician was present at the meeting and chaired the task force meeting. As the chairperson, he or she assured that everyone's opinions were heard and each aspect was fully discussed. (Ex. 115, Test. Dr. Cain 158-59.)

* An African-American OB/GYN who is affiliated with a university and treats primarily an uninsured and immigrant population. The physician had performed abortions and had overseen or performed the intact D & X, as defined by ACOG. This physician was unable to attend the task force meeting. (Ex. 115, Test. Dr. Cain 62-63 & 199.)

* An OB/GYN practicing at a university in the area of maternal-fetal medicine and ultrasound who has performed abortions. This physician may have overseen or performed the intact D & X, as defined by ACOG. (Ex. 115, Test. Dr. Cain

64-65 & 198.) This physician was present at the meeting. (Ex. 115, Test. Dr. Cain 158.)

* The chief of a university medical facility who approached the task force from the viewpoint of maternal health and had experience in performing abortions. This physician had overseen and performed the intact D & X, as defined by ACOG, and was present at the meeting. (Ex. 115, Test. Dr. Cain 67, 158, 198-99.)

* A practicing OB/GYN with experience in treating maternal complications during pregnancy. This physician opposes abortion and would not have overseen or performed the intact D & X, as defined by ACOG. This physician was not present at the meeting. (Ex. 115, Test. Dr. Cain 67-68, 70, 158, 198.)

* The chair of a university department of obstetrics and gynecology who has abortion experience and has written textbooks on maternal-fetal medicine. This physician had overseen performance of the intact D & X, as defined by ACOG. This physician was not present at the meeting. (Ex. 115, Test. Dr. Cain 68-69, 158, 198-99.)

* A practicing OB/GYN with expertise in providing abortions who had overseen and performed the intact D & X, as defined by ACOG. This physician was present at the meeting. (Ex. 115, Test. Dr. Cain 69, 158, 198-99.)

The meeting of the task force was held on October 5-6, 1996. The members met at a working dinner and documents were reviewed. The members were then

required to review the materials over the evening to prepare for their discussion at the meeting. (Ex. 115, Test. Dr. Cain 79-80.)

At the task force meeting, the members reviewed the intact D & X procedure in detail and together crafted language they believed represented expert opinion on the issues of concern to the fellowship. A staff member typed the draft language and it was then edited by the committee. (Ex. 115, Test. Dr. Cain 80.) As different topics were discussed, a member would volunteer to try to put the discussion into written words for editing by the committee. Separate paragraphs were circulated for comment, as was the entire document. (Ex. 115, Test. Dr. Cain 84-87.)

iii. INTACT D & X TASK FORCE DELIBERATION

Exhibit 8 is the agenda for the October 1996 task force meeting. (Ex. 115, Test. Dr. Cain 158.) The documents provided to task force members by ACOG for consideration included:

* *Exhibit 656:* A letter written by President Clinton concerning the reason he vetoed H.R. 1833, proposed legislation banning "partial-birth abortion." This letter was used to identify the public's questions and concerns for consideration in formulating the ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 88-90 & Ex. 656.)

* *Exhibit 657:* A letter sent by Dr. David Grimes to Senator Robert C. Byrd regarding the partial-birth abortion ban. This letter was used to identify medical and ethical issues to be considered in formulating the ACOG Statement on Intact Dila-

tion and Extraction. Although Dr. Grimes is a well-regarded expert and leading authority in the area of abortion, his letter to the senator was not used to provide a medical basis for the ACOG Statement on Intact Dilation and Extraction. The task force did not receive or review letters from other doctors in the field of obstetrics. (Ex. 115, Test. Dr. Cain 94-99, 148 & Ex. 657.)

* *Exhibit 658:* A National Abortion Federation question and answer sheet entitled "Later Abortions: Questions and Answers." This document was used to identify common questions to be considered in formulating the ACOG Statement on Intact Dilation and Extraction, and examples of medical situations discussed in Exhibit 658 were considered by the task force. Exhibit 658 was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 100-03 & Ex. 658.)

* *Exhibit 659:* The statement of the National Abortion Rights Action League entitled "Third-trimester Abortion: The Myth of 'Abortion on Demand.'" This document was used to identify specific medical circumstances a woman and physician may face. The task force members reviewed the specific examples referenced in Exhibit 659, along with others raised by the task force members, and considered whether, in the context of their own practice and expertise, the intact D & X procedure was the most appropriate abortion method to be used under the circumstances. The medical records of the patients

discussed in Exhibit 659 were not available to the task force. (Ex. 115, Test. Dr. Cain 103-06 & Ex. 659.)

* *Exhibit 660:* A National Abortion Federation document entitled "Fact Sheet. Abortion after Twelve Weeks." This document was used to identify areas for task force consideration. The document was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 106-09 & Ex. 660.)

* *Exhibit 661:* A National Abortion Federation document entitled "Second trimester Abortion: From Every Angle, Fall Risk Management Seminar, September 13-14, 1992, Dallas, Texas." The document included a paper by Martin Haskell. Exhibit 661 was used to provide background concerning the intact dilation and extraction procedure from the viewpoint of a provider who performs the procedure, and it explained the various methods used to describe the procedure. The Haskell paper was used solely to define the procedure for the policy statement. Other than that, it was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 109-12 & 176:3-22, Ex. 661.)

* *Exhibit 662:* A brochure published by the Wisconsin Right to Life Education Fund entitled, "The D & X Abortion Procedure: Scientific Advancement or Human Rights Abuse?" This document was used to identify areas for task force consideration and contains graphic images of the intact D & X procedure. These images were discussed, and the document was used as

an example of how disseminated literature defines the dilation and extraction procedure. It was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 115-17 & Ex. 662.)

* *Exhibit 663:* An article written by Dr. Allen Rosenfield and published by the New York Times. Dr. Rosenfield is an obstetrician-gynecologist and was the dean of the Columbia School of Public Health, a preeminent school of public health in the United States. This document was used to provide general background concerning the use of the dilation and extraction abortion procedure. The Rosenfield article commented on ACOG's concern with Congress superseding medical judgment. Since the document did not contain statistical information deemed appropriate for reaching a medical conclusion, it was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 118-20 & Ex. 663.)

* *Exhibit 664:* A New York Times editorial entitled "Abortion Politics." This document was used to provide general background concerning the use of the dilation and extraction abortion procedure. It also stated that the terminology used by Congress is not recognized in the medical community. It was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 120-21 & Ex. 664.)

* *Exhibit 665:* "The Partial-Birth Abortion Act of 1995," with a subtitle "Medical Assertions Made in the Debate on HR 1833." The document con-

tains quotes from the congressional debate on the 1995 version of the Act. These quotes were compiled by ACOG staff for the task force's deliberation. The task force did not review the congressional record itself. Exhibit 665 also contained data from Dr. McMahon which was included in the congressional record. The examples of maternal fetal indications discussed in Exhibit 665 were used by task force members to expand their discussion and consider the intact D & X procedure in the context of the members' own practice and expertise. It raised questions concerning possible medical complications, but it was not relied on to answer those questions. (Ex. 115, Test. Dr. Cain 121-22, 125-28, 147-48, Ex. 665.)

* *Exhibit 666:* A memorandum to the task force on third-trimester abortion written by Kathy Bryant, who is a lawyer and the Associate Director of ACOG's Department of Government Relations. An ACOG document entitled, "Medical Questions and Answers on Third Trimester Termination Procedures," was attached to the memorandum. Exhibit 666 noted that many terms were being used to describe the intact D & E or D & X procedure. The task force believed that much of the confusion regarding partial-birth abortion arose from the fact that there was no clearly delineated description of the procedure. The task force, and ultimately ACOG, defined the procedure and gave it a name. (Ex. 115, Test. Dr. Cain 129-32, 161-62, Ex. 666.)

* *Exhibit 667:* An exhibit compiling the ACOG document entitled "Medical Questions and Answers on Third Trimester Abortion Procedures," Dr. Frigoletto's letter in response to that document, and Dr. Murray Nusbaum's letter to Dr. Penny Murphy in response to Dr. Frigoletto's letter. (Ex. 115, Test. Dr. Cain 135-36 & Ex. 667.)

* *Exhibit 668:* An October 3, 1996, memorandum on third-trimester abortion from Elsa P. Brown which provided the "additional background material requested by Dr. Frigoletto." This document was used to provide general background information and statistical information from the Centers for Disease Control and the Alan Guttmacher Institute. (Ex. 115, Test. Dr. Cain 137-38 & Ex. 668.)

* *Exhibit 671:* Letters sent by Dr. Robert Hale, as the executive director of ACOG, to President Clinton and Senator Dole. (Ex. 115, Test. Dr. Cain 156-57.)

* *Exhibit 9:* A 1987 ACOG technical bulletin. At the time it was written, labor was induced with hypertonic saline and urea. The document was likely available to the task force, and may have been discussed in terms of the relative safety of induction and D & E based on gestational age. It would have been discussed along with other information that may have superseded this 1987 bulletin. (Ex. 115, Test. Dr. Cain 183-86 & Ex. 9.)

In forming the task force's proposed ACOG Statement on Intact Dilation and Extraction, the members relied on their own education and expertise, obstetrics and gynecology textbooks, CDC information, published information on the safety of D & E and the D & X subset of D & E, and information about the safety of available alternatives. The textbooks were referenced for information about specific abortion procedures. The task force did not rely on information received from the public, did not interview or receive testimony from doctors, and did not draft and circulate individual position papers or statements for review and comment by other task force members. (Ex. 115, Test. Dr. Cain 143-47, 149-50, 171-73.) Before and during the task force meeting, neither ACOG nor the task force members conversed with other individuals or organizations, including congressmen and doctors who provided congressional testimony, concerning the topics addressed in the ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 151-55.)

Dr. Cain does not specifically recall any document reviewed by the task force comparing the relative safety of induction versus D & E. The task force discussed the findings of Haskell and McMahon regarding the relative safety of the intact D & X procedure, but it did not rely on these articles in reaching its conclusions on the relative safety of the intact D & X. (Ex. 115, Test. Dr. Cain 186-88.)

To the extent they were part of the textbook literature available to the task force, the articles published by Dr. Grimes in the 1980s were likely considered by the task force in drafting the proposed ACOG Statement on Intact Dilation and Extraction. The task force did not discuss Dr. Grimes's 1983 conclusion with re-

spect to the relative state of D & E and induction after 16 weeks of gestation. (Ex. 115, Test. Dr. Cain 179-81.) The task force did not request additional information from ACOG. (Ex. 115, Test. Dr. Cain 148.)

In considering the relative safety of abortion procedures, the committee discussed patient factors such as the woman's general state of health, the nature of the disease process, other options available and their particular risks in light of that patient's specific medical circumstances, and the patient's autonomous choice among the options presented. (Ex. 115, Test. Dr. Cain 231-32.) The task force considered the cases discussed by its members as examples of when an intact D & X may be the safest procedure, but these were not published case reports. There are no randomized prospective studies demonstrating that the intact D & X may be the best or most appropriate procedure in certain circumstances. (Ex. 115, Test. Dr. Cain 195-97 & 203-04.)

The task force relied on CDC data regarding the overall safety of D & E for second-trimester abortions. It recognized that the procedure it defined as intact D & X was primarily performed in the second trimester starting at 18 weeks of gestation; however, the data concerning the safety of the intact D & X was not separately documented from D & E data and was therefore not well-defined. (Ex. 115, Test. Dr. Cain 174-79.) Task force members were, however, able to think of individual patient circumstances where the intact D & X was a better choice for the individual patient. These circumstances were discussed during the deliberation on the proposed ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 210 & 229.) For example, with a form of cancer of the placenta most often

diagnosed in the second trimester and associated with severe preeclampsia, instrumentation on the uterine wall should be avoided as much as possible. In such a case, it is much safer for the woman to have an intact D & X procedure to remove the molar pregnancy. (Ex. 115, Test. Dr. Cain 177.) At least 25 to 30 different types of cases were discussed among the task force members. (Ex. 115, Test. Dr. Cain 201.)

Ethical issues were considered as part of the task force deliberation process. The sentence of the policy which states "[t]he physician, in consultation with the patient, must choose the most appropriate method based upon the patient's individual circumstances" factors in the three key elements of medical ethics decision-making in the United States and worldwide. (Ex. 115, Test. Dr. Cain 230 & 236-37.)

iv. EXHIBIT 655: TASK FORCE'S PROPOSED ACOG STATEMENT ON INTACT DILATION & ETRACTION

Exhibit 655 is the proposed ACOG Statement on Intact Dilation and Extraction that was sent to the board from the task force. (Ex. 115, Test. Dr. Cain 80-81, 159; Ex. 655.)

The first paragraph of the proposed ACOG Statement on Intact Dilation and Extraction discusses the general background of "partial-birth abortion" and acknowledges the existence of broad and inconsistent definitions for the term. The second and third paragraphs present a clear medical definition of the procedure within the practice of obstetrics. The paragraph relating to the general safety of second-trimester abortion was based on the materials provided to the task

force.[107] The final paragraph stated ACOG's concern with legislation that may prohibit specific medical techniques that are critical to the lives and health of American women. (Ex. 115, Test. Dr. Cain 82-84.)

(a) THE DEFINITION OF INTACT D & X

The task force's definition of "intact D & X" included the four elements listed in the ACOG Statement on Intact Dilation and Extraction. Based on this definition, an intact D & X requires instrumental conversion of the fetus to a footling breech. ACOG's definition of the intact D & X has not changed since 1997. (Ex. 115, Test. Dr. Cain 164-66.) Removal of intracranial contents as described in ACOG's intact D & X definition includes more than removal of the fetus's cerebral spinal fluid. (Ex. 115, Test. Dr. Cain 169-70.)

(b) THE CONCLUSION

The proposed ACOG Statement on Intact Dilation and Extraction submitted by the task force (Ex. 655) concluded that it could identify no circumstances where the intact D & X was the only available option to save the life of the woman or preserve her health. The task force had discussed numerous circumstances where it may be the best procedure for the woman's life and health, and therefore stated that the decision should be left to the woman and her doctor. Exhibit 655 did not, however, specifically state that the intact D & X was

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[107] Exhibit 668, the October 3, 1996, memorandum on third-trimester abortion drafted by Elsa P. Brown and providing the "additional background material requested by Dr. Frigoletto" was not the basis for the CDC statistical information contained in the ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 138-39.)

sometimes the safest and best available procedure. (Ex. 115, Test. Dr. Cain 189-91, 194-95, 208.)

As reflected in Exhibit 655, ACOG and the task force are strongly opposed to the intervention by legislative bodies in medical decision making between the patient and doctor. ACOG believes legislative intervention may have the unintended side effect of outlawing medical procedures that may be best for the woman's health and well-being, and in doing so, may cause harm to women. (Ex. 115, Test. Dr. Cain 211-14.)

The proposed ACOG Statement on Intact Dilation and Extraction did not identify any studies concerning the relative safety of the intact D & X (Ex. 115, Test. Dr. Cain 178 & Ex. 655), and the task force reached no conclusions regarding how frequently the intact D & X is performed. (Ex. 115, Test. Dr. Cain 188-89.)

v. EXHIBIT 6: ACOG STATEMENT ON INTACT DILATION & EXTRACTION

Exhibit 11 is the report provided to the ACOG executive board by Dr. Frigoletto regarding the task force's proposed ACOG Statement on Intact Dilation and Extraction (Ex. 655; Ex. 115, Test. Dr. Cain 142-43; Ex. 11.) The executive board edited the task force's proposed policy by adding, "[a]n intact D & X, however, may be the best or most appropriate procedure to save the life or preserve the health of a woman." The additional phrasing was consistent with the task force's discussion. (Ex. 115, Test. Dr. Cain 191-94.)

Exhibit 6 is the January 1997 statement of policy regarding the intact D & E which was adopted by ACOG pursuant to its general policy-drafting and adoption processes. (Ex. 115, Test. Dr. Cain 38-39 & 219-20.) As with any other ACOG policy statements, the ACOG

Statement on Intact Dilation and Extraction was not submitted for vote of approval by the membership of the College. (Ex. 115, Test. Dr. Cain 76-77.) Once approved by the executive board, the ACOG Statement on Intact Dilation and Extraction was disseminated to the membership (fellows) of ACOG. Although forums can be held at the ACOG annual meetings to discuss policy statements, and annual meetings were held after the 1997 ACOG Statement on Intact Dilation and Extraction was approved and after it was re-affirmed in 2000, Dr. Cain is not aware of any forums conducted regarding the ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 53-55 & 233.)

vi. EXHIBIT 5: ACOG STATEMENT-ABORTION POLICY

Exhibit 5 is ACOG's September 2000 statement on abortion policy. The ACOG Statement on Intact Dilation and Extraction (Ex. 6) was inserted verbatim into ACOG's overall statement of abortion policy. Exhibit 5, the ACOG statement of abortion policy, was prepared in the course of ACOG's business pursuant to ACOG's general procedures for drafting, adopting, and issuing policy statements on behalf of the College. (Ex. 115, Test. Dr. Cain 29, 210-11, 220-22; Ex. 5.)

vii. EXHIBIT 7: ACOG FACT SHEET

Exhibit 7 is the fact sheet prepared by ACOG staff concerning the January 1997 ACOG policy statement regarding intact D & X. The document was prepared in the normal course of ACOG's business to further explain to ACOG fellows the issues regarding intact D & X. Fact sheets such as Exhibit 7 are not adopted by the executive board. (Ex. 115, Test. Dr. Cain 39 & 227-29.) The fact sheet was written by ACOG staff and sent to

task force members for comment. (Ex. 115, Test. Dr. Cain 78-79.)

b. APHA

Mr. Alan Baker is the Chief of Staff for the American Public Health Association ("APHA"). He was the designated 30(b)(6) witness for the APHA. (Ex. 117, Test. Baker 7-8 & 45.)

APHA is a membership association comprised of people interested or working in public health from a multitude of backgrounds, including doctors, medical researchers, epidemiologists, nurses, health educators, social workers, and statisticians. APHA has approximately 50,000 direct and charter members. Its members are predominantly from the United States, but there are also members from Canada, Mexico, and Europe. (Ex. 117, Test. Baker 30, 33, 45-48.)

APHA policies are member-initiated. On a yearly cycle, APHA posts publications on its website so members can act to initiate proposals for policies on issues not addressed by current APHA policy. APHA is divided into sections for public health nursing, health administration, and epidemiology. Members belong to the section of their choice. A section committee or an individual member may choose to initiate a new APHA policy by preparing a draft policy. A member or committee initiating a proposed policy has chosen to work on it and has a sincere interest and often significant expertise on the topic. The drafting individual or committee will sometimes cite to scientific and peer-reviewed literature in support of a policy proposal. The proposed policy is then submitted to the APHA action board. Members of the action board serve at the appointment of the APHA executive board. The action board re-

views and/or revises the policy and distributes it to other APHA sections and member groupings. At the APHA annual meeting, the policy review committee discusses, reviews, and possibly revises the policy proposal. It may then be advanced to the APHA governing council. (Ex. 117, Test. Baker 30-32 & 33.)

The APHA governing council is comprised of representatives from each state and the past presidents of the association. There are approximately 200 APHA governing council members. Proposed policies are presented to the governing council, which may discuss the policy at length, amend the policy, or change its wording. Policies are voted on by the governing council. (Ex. 117, Test. Baker 32-33.)

Exhibit 18, pages 00003-00006, are copies of 1981 and 1989 APHA policy statements adopted in accordance with APHA procedure. These policies set forth APHA's position on constitutional amendments or statutes which prohibit abortion (the 1981 policy) and the duties of members to safeguard the right to abortion as a reproductive choice (the 1989 policy). (Ex. 117, Test. Baker 34; Ex. 18.)

Exhibit 17 is a letter from the APHA executive director to the House of Representatives. Exhibit 17 was primarily prepared by APHA's director of federal and congressional relations. No particular members of APHA were contacted regarding the preparation of Exhibit 17. While the letter reflects the application of APHA's long-standing policies on abortion to the proposed partial-birth abortion legislation, the letter itself is not a policy adopted though the APHA policy-review process. The content of the letter was discussed with APHA's assistant director for policy and the association's executive director. The letter was part of a "mail

drop," a collection of letters from organizations of like mind which were submitted as a packet of material to Congress. Pro-Choice America organized and coordinated the mail drop. (Ex. 117, Test. Baker 9-14, 18-19, 24, 34-35; Ex. 17.)

The Exhibit 17 letter is an APHA statement to Congress opposing the Partial-Birth Abortion Ban Act because the Act fails to include an adequate health exception allowing the physician to determine the best or most appropriate procedure to preserve the health of the woman. This opposition statement was based on the professional knowledge of the APHA officers involved in creating the letter, APHA's 1981 long-standing and officially adopted policy supporting the woman's right to choose, and APHA's 1989 policy stating that public health workers have a duty to challenge congressional actions or proposed constitutional amendments which would impact the woman's right to choose. The letter was signed by Georges C. Benjamin, M.D., the APHA executive director. (Ex. 117, Test. Baker 21-23, 25-29, 55; Ex. 17.)

c. AMWA

Ms. Meghan Kissell, the director of communications and advocacy for the American Medical Women's Association ("AMWA"), was the designated 30(b)(6) witness for the AMWA. (Ex. 116, Test. Kissell 8 & 84-86.) The AMWA is an association of 10,000 female medical professionals dedicated to advancing women in medicine and improving women's health. Some of the members are obstetricians and gynecologists that perform abortions. (Ex. 116, Test. Kissell 10 & 86.)

Exhibit 16 is the set of records provided by AMWA to the Department of Justice in response to the gov-

ernment's subpoena. Exhibit 16, pages 00003-00006, are the AMWA position statements on abortion and access to comprehensive reproductive health services. Position statements of the AMWA are reviewed and approved by the organization's members and its board of directors. (Ex. 116, Test. Kissell 11-13.)

Ms. Kissell testified that the AMWA has not issued a formal position statement on the Partial-Birth Abortion Ban Act of 2003 or any of the Act's underlying bills. (Ex. 116, Test. Kissell 13-14.) However, Ms. Kissell also testified that Exhibit 14 is a March 25, 2003, letter opposing HR 760, the "Partial-Birth Abortion Ban Act of 2003," and Exhibit 15 is a July 18, 2002, letter opposing HR 4965, the "Partial-Birth Abortion Act of 2002." Kissell testified that these letters are the current position statements of the AMWA and were subjected to the AMWA's position-statement-approval process. (Ex. 116, Test. Kissell 91-92.)

The blackened box in the middle of page AMWA 00012 of Exhibit 16 references the process for proposing and responding to resolutions. An AMWA member may propose that the association take a position on an issue. A member proposal is called a resolution. The resolution is considered through a formal process which culminates with a meeting of the members. No resolutions have been proposed to the AMWA regarding the Partial-Birth Abortion Ban Act of 2003 or 2002. (Ex. 116, Test. Kissell 26-28.)

The AMWA may also act on behalf of the association by advancing positions in amicus briefs, court cases, and correspondence to members of Congress. (Ex. 116, Test. Kissell 29-30.) Exhibit 14 is a letter from the president of AMWA to Congressman Jerrold Nadler regarding the Partial-Birth Abortion Ban Act of 2003.

It is very similar to the letter AMWA sent regarding the Partial-Birth Abortion Act of 2002. The letter was based on the position papers of the AMWA and was consistent with its amicus brief in *Carhart v. Stenberg*. As the AMWA Director of Communications and Advocacy, Ms. Kissell generated the 2003 letter as a near duplicate of the letter previously submitted by the association on the 2002 proposed Act, the president signed it, and the executive director was notified that the letter was sent. The board of directors did not direct her to prepare the 2003 letter, and the membership was not asked to and did not respond to its content. The position of AMWA has not changed since the 2002 letter (Ex. 15) was sent. (Ex. 116, Test. Kissell 31-35; Ex. 14.)

The second sentence of Exhibit 14 states that the proposed Partial-Birth Abortion Ban Act would ban a procedure that in some circumstances is the safest and most appropriate alternative for the life and health of the woman. The letter was directed at late-term abortion procedures. AMWA believes doctors should retain the option of choosing the most appropriate procedure for a woman at the time she chooses to terminate a pregnancy. (Ex. 116, Test. Kissell 39-41; Ex. 14.)

The organizational position related in Exhibit 14 is that the Act is imprecise, does not include correct medical terminology, and that choosing the appropriate abortion procedure in a specific case should be left to the doctor and not the government. The question of whether the letter was directed at a particular abortion procedure must be answered by the AMWA's expert members. (Ex. 116, Test. Kissell 43-45.)

Exhibit 15 is a letter from the president of AMWA to Congressman Steve Chabot regarding the Partial-

Birth Abortion Act of 2002. The AMWA had opposed similar bans in the past, and the documents opposing previous bans were reviewed by past government affairs chairmen, executive directors, women's health committees, and chairmen of the advocacy committee. The letter also references AMWA's involvement in the amicus brief in *Carhart v. Stenberg*. Ms. Kissell prepared the Exhibit 15 letter for the president's signature. No other AMWA staff saw or assisted in preparing the letter. (Ex. 116, Test. Kissell 54-57; Ex. 15.)

AMWA is in coalition with organizations that have legal counsel, including the Pro-Choice Lobby Group. The AMWA's position that the bill was imprecise, included non-medical terminology, and could ultimately undermine the legality of other techniques used in obstetrics and gynecology was based on discussions with organizations other than AMWA that had legal counsel. (Ex. 116, Test. Kissell 75-77.)

Exhibits 14 and 15 are the current position statements of the AMWA and were subjected to the AMWA's position-statement-approval process. The AMWA presidents who signed the 2003 letter (Ex. 14) and the 2002 letter (Ex. 15) were physicians. (Ex. 116, Test. Kissell 91-92, 94-95; Exs. 14 & 15.)

6. ENFORCEMENT OF THE ACT

Mr. Wan J. Kim, a graduate of the University of Chicago law school and a deputy assistant attorney general with the United States Department of Justice, was identified by the government as the person within the Department of Justice who has knowledge concerning how the Partial-Birth Abortion Ban Act of 2003 will be enforced. Pursuant to a 2003 political appointment, Mr. Kim is assigned to the Civil Rights Division

which enforces statutes, mainly in discrimination matters. Assuming enforcement of the Act is not permanently enjoined, the Civil Rights Division will be charged with the responsibility of enforcing the Partial-Birth Abortion Ban Act of 2003. (Ex. 118, Test. Kim 14-18 & 24.)

To Mr. Kim's knowledge, the Department of Justice has not adopted a policy or position regarding how the Act will be enforced if it is not enjoined. (Ex. 118, Test. Kim 38-42.) Exhibit 42 is the department's directive to the FBI field offices from its Criminal Investigation Division concerning the Partial-Birth Abortion Ban Act of 2003. (Ex. 118, Test. Kim 102-103.) Under this directive, the Federal Bureau of Investigation is not to investigate any complaint concerning an alleged violation of the Act without first forwarding the complaint to the Civil Rights Division for an initial determination. Enforcement of the Act is to be coordinated by a task force within the criminal enforcement section of the Civil Rights Division, but this task force has not been formed. (Ex. 118, Test. Kim 24, 32-34, 79.)

a. THE FIELD GUIDANCE DOCUMENT

Mr. Kim was the principal author of the document entitled "Field Guidance on New Criminal Authority Enacted in The Partial-Birth Abortion Ban Act of 2003," which was an attachment to the Department of Justice's November 5, 2003, memorandum on implementation of the Partial-Birth Abortion Ban Act of 2003 (Ex. 40). The field guidance document was intended to explain the law to United States Attorneys, Assistant United States Attorneys, and FBI agents. Field guidance documents are often, but not always, generated by the Department of Justice when new statutes are enacted. The field guidance document Mr. Kim wrote con-

cerning the Partial-Birth Abortion Ban Act of 2003 is the only statement of policy by the Department of Justice regarding interpretation and enforcement of the Act. (Ex. 118, Test. Kim 68-73, 75-76, 120; Ex. 40, at ENF 00011-00012.)

The field guidance document identifies two essential elements for finding a violation of the Act: (1) a physician must knowingly perform a partial-birth abortion, thereby killing a human fetus, and (2) the violation must be in or affecting interstate or foreign commerce. These elements were gleaned from the plain language of the Act. (Ex. 118, Test. Kim 84-85; Ex. 40, at ENF 00011.) Under the terms of the field guidance document, partial-birth abortion is defined to incorporate "two separate and sequential acts: (1) the partial delivery of a living fetus and (2) an overt act that kills a partially delivered living fetus." This definition arises from the plain language of the Act as interpreted by the Attorney General. (Ex. 118, Test. Kim 85-86; Ex. 40, at ENF 00011.) The Department of Justice has not, however, made a formal and final decision or created a policy defining "partial delivery," "living fetus," or "overt act," and these terms are not defined in the field guidance document. (Ex. 118, Test. Kim 87; Ex. 40, at ENF 00011-00012.)

b. PROSPECTIVE ENFORCEMENT

In the context of criminal enforcement, Mr. Kim is required to interpret statutory language to decide whether the government will prosecute under the specific facts raised in a case. (Ex. 118, Test. Kim 20-21.) He is not aware of any policies or guidance within the Department of Justice concerning what specific procedures are covered by the Partial-Birth Abortion Ban

Act. To his knowledge, those decisions have not been made. (Ex. 118, Test. Kim 42-44 & 68.)

Assuming the injunction barring enforcement of the Act were lifted tomorrow, if the Department of Justice receives a complaint alleging a violation of the Act, the allegation will be investigated. After the facts are collected, the department will determine what procedures fall within the scope of the Act's prohibition and whether the facts justify prosecution. Decisions as to prospective application of the Act will probably be made by attorneys within the Department of Justice in the context of specific cases. (Ex. 118, Test. Kim 92-94 & 98-99.) When asked how a physician would know what conduct fell within the scope of the Act's prohibitions, Mr. Kim responded:

> You're asking me to speculate. I would speculate . . . the NAF would probably issue guidance. Physicians may look up-I don't know. I really don't know. I mean, I assume they would read the act, but I don't know the physician you're talking about.

(Ex. 118, Test. Kim 90-91.)

To date, the Department of Justice has not made a final policy decision as to whether, for the purposes of the Act, a physician commits a lethal overt act for the purposes of the Act by cutting the fetus's umbilical cord, collapsing the fetal skull or suctioning out its contents, crushing the fetal trunk, or dismembering the fetus. (Ex. 118, Test. Kim 89 & 124-26.) The Department of Justice has made no final policy decision as to whether a physician violates the Act by performing a partial-birth abortion when a hysterectomy or hysterotomy were available options to save the patient's life. (Ex. 118, Test. Kim 101-02 (Mr. Kim acknowledges

that he does not know what some of these medical terms mean).) It has formulated no final policy concerning whether the Act bans only late-term abortion procedures, how early in pregnancy the Act will apply, or whether it will be enforced before the fetus is viable (Ex. 118, Test. Kim 115 & 122-23); whether the Act bans abortions involving suctioning the uterus, dismemberment D & Es, or labor-induction abortions (Ex. 118, Test. Kim 119-20 & attached errata sheet); or whether the Act will be enforced when procedures are performed on nonviable fetuses. (Ex. 118, Test. Kim 65-66.)

Dr. Broekhuizen testified that physicians are not certain whether particular situations would be covered by the Act such that the Department of Justice would pursue enforcement. For example, a woman was referred to Dr. Broekhuizen for a medically necessary abortion at 23 weeks and one day. She had scleroderma with pulmonary hypertension and significant vascular disease. The doctors believed she faced serious and potentially life-threatening complications if she underwent the stress of labor or was given anesthesia, and the use of prostaglandins (including misoprostol) was contraindicated. Dr. Broekhuizen treated her with three sets of serial laminaria for approximately 24 to 30 hours. Although the dilation was sufficient to permit the fetus to deliver intact without compressing the fetal head, at the outset of the procedure he intended to perform an intact D & E. (Ex. 120, Test. Dr. Broekhuizen 537-38, 592, 594-95.) It is not clear whether those who would enforce the Act would consider this situation suf-

ficiently life-threatening to be covered by the Act's exception.[108] (Ex. 120, Test. Dr. Broekhuizen 558-59.)

II. LAW

Condensed, the plaintiffs assert four arguments. First, they argue that the ban is unconstitutional because it lacks an exception for the health of women. Second, they argue that the ban is unconstitutional because it threatens to reach other needed abortion procedures or medical techniques, specifically, second-trimester previability D & E and induction abortions and treatment methods used for spontaneous abortions (miscarriages). Thus, they claim, the ban is an undue burden on women. Third, they argue that the ban is unconstitutional because it is vague; that is, the statute fails to clearly define the banned procedure and, more generally, the statute uses vague words. Finally, they argue that the ban's "life" exception is unconstitutional because it permits use of the banned procedure only when "necessary" as opposed to when "necessary in appropriate medical judgment."

With some important qualifications, I agree that the ban is unconstitutional for the first three reasons asserted by the plaintiffs. Specifically, the law is unconstitutional because: (1) it lacks a health exception; (2) accepting Mr. Ashcroft's proposed "specific intent" limiting construction, the law nevertheless bans D & E abortions of the type performed by Dr. Carhart when he does not first induce fetal death by injection prior to

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[108] His concern may not be unwarranted given the level of second-guessing by the government and its extensive cross-examination regarding Dr. Broekhuizen's decision. (Ex. 120, Test. Dr. Broekhuizen 591-99.)

18 weeks;[109] and (3) if Mr. Ashcroft's proposed "specific intent" limiting construction is improper, the law is too vague regarding the behavior the law seeks to criminalize.

I do not agree that the law, properly limited, bans certain D & E abortions where the physician lacks the requisite specific intent. Similarly, when a physician conducts induction abortions or when a physician treats spontaneous abortions, he or she lacks the requisite specific intent and therefore the law does not ban those activities. Moreover, I do not believe the law is too vague because of the use of certain words.

In addition, I do not agree that the ban's "life" exception is unconstitutional, although, again, only a limiting construction by this court saves it from Congress' deficient drafting. I must read into the ban's "life" exception the important clarification urged by Mr. Ashcroft; that is, "The Act's life exception is subject to a . . . construction that permits a physician to perform a partial-birth abortion if 'necessary,' in his or her own professional judgment, 'to save the life of the mother[.]'" (Filing 161, Def.'s Br. at 98) (citing *U.S.* v. *Vuitch*, 402 U.S. 62, 72, 91 S. Ct. 1294, 28 L. Ed. 2d 601 (1971).)

Moreover, I do not agree with the plaintiffs that I should declare this law unconstitutional with respect to abortions where the fetus is undisputably viable. There was little or no evidence presented to me on what really

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[109] Whether because the law does not contain a health exception or because it bans certain D & E abortions, the effect of the law is an undue burden as it places a substantial obstacle in the path of women seeking an abortion of a nonviable fetus. I decline to decide whether that was its purpose.

happens during this gestational stage. Moreover, none of the plaintiff-doctors perform abortions on fetuses that are obviously viable in order to preserve the health, as opposed to the life, of women. Therefore, I decline to determine whether the law is constitutional or unconstitutional when the fetus is undisputably viable. In other words, my ruling is limited to deciding that the law is unconstitutional in all circumstances where the fetus is either not viable or where there is a doubt about the viability of the fetus in the appropriate medical judgment of the doctor performing the abortion.

Finally, and out of deference to the other federal courts that have simultaneously heard similar challenges, I will limit the reach of the injunction that I issue to these plaintiffs and their associates. That is, I decline to issue a "nationwide" injunction.

A. BECAUSE IT CONTAINS NO HEALTH EXCEPTION, THE BAN IS UNCONSTITUTIONAL.

1. A STATUTE RESTRICTING A PARTICULAR ABORTION METHOD MUST PROVIDE AN EXCEPTION FOR THE HEALTH OF THE WOMAN WHERE SUBSTANTIAL MEDICAL AUTHORTY ESTABLISHES THAT BANNING THAT PROCEDURE COULD SIGNIFICANTLY ENDANGER THE WOMAN'S HEALTH.

In *Stenberg* v. *Carhart*, 530 U.S. 914, 120 S. Ct. 2597, 147 L. Ed. 2d 743 (2000) (hereinafter *Stenberg*), the Supreme Court upheld this court's determination that a Nebraska law banning "partial-birth abortion" was unconstitutional because, among other reasons, the law failed to include an exception for the health of women. Obviously, that case is very similar to this one. Dr.

Carhart was the plaintiff in *Stenberg*, and he is a plaintiff in this case. The law in *Stenberg* sought to ban "partial-birth abortion" and the law here seeks to ban "partial-birth abortion." Still further, the federal law challenged here explicitly attacked the factual findings of this court in *Stenberg*. Because of the close legal and factual similarity between *Stenberg* and this case, I must be guided primarily by the principles laid down by the Supreme Court in *Stenberg*.[110]

The core legal principle of *Stenberg* is this: While the government is not required to "grant physicians 'unfettered discretion' in their selection of abortion methods[,] . . . where substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women's health," the Constitution "requires the statute to include a health exception when the procedure is "'necessary, in appropriate medical judgment, for the preservation of the . . . health of the mother.'"" *Id.* at 938, 120 S. Ct. 2597 (quoting *Casey*, 505 U.S. at 879, 112 S. Ct. 2791, in turn quoting *Roe v. Wade*, 410 U.S. at 164-65, 93 S. Ct. 705). That primary rule is premised upon the following precepts:

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[110] Of course, I recognize that the law dealt with by *Stenberg* was a state law and the law at issue here is a federal law, but I do not believe that such a difference makes a relevant distinction in terms of the right to an abortion. Whatever the constitutional source of abortion rights, those rights have always been understood to apply equally to the federal and state governments and Mr. Ashcroft does not contend otherwise. Indeed, when questioned on this point, Mr. Ashcroft's able counsel affirmatively stated that he was not urging the court to make such a distinction. (Tr. 1866.) Based upon that representation, I pursue this matter no further.

* "[T]he Constitution offers basic protection to the woman's right to choose." *Id.* at 921, 120 S. Ct. 2597.

* "[B]efore 'viability . . . [,] the woman has a right to choose to terminate her pregnancy.'" *Id.* (quoting *Casey*, 505 U.S. at 870, 112 S. Ct. 2791 (omission in original)).

* A "'law designed to further [the government's] interest in fetal life which imposes an undue burden on the woman's decision before fetal viability' is unconstitutional." *Id.* (quoting *Casey*, 505 U.S. at 877, 112 S. Ct. 2791).

* The phrase "'undue burden'" is "'shorthand for the conclusion that a [governmental] regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.'" *Id.* (quoting *Casey*, 505 U.S. at 877, 112 S. Ct. 2791).

* After "'"viability, the [government] in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."'" *Id.* (quoting *Casey*, 505 U.S. at 879, 112 S. Ct. 2791, in turn quoting *Roe v. Wade*, 410 U.S. at 164-65, 93 S. Ct. 705).

* "The word 'necessary' in *Casey's* phrase 'necessary, in appropriate medical judgment, for the preservation of the life or health of the mother,' cannot refer to an absolute necessity or to abso-

lute proof." *Id.* at 937, 112 S. Ct. 2791 (citation omitted). Nor does " 'necessary, in appropriate medical judgment' . . . require unanimity of medical opinion." *Id.* These words "tolerate responsible differences of medical opinion. . . ." *Id.*

* The government's "interest in regulating abortion previability is considerably weaker than postviability." *Id.* at 930, 112 S. Ct. 2791. Therefore, "[s]ince the law requires a health exception in order to validate even a postviability abortion regulation, it at a minimum requires the same in respect to previability regulation." *Id.*

* The government "cannot subject women's health to significant risks" and that principle applies "where [governmental] regulations force women to use riskier methods of abortion." *Id.* at 931, 112 S. Ct. 2791. That is, the Court's "cases have repeatedly invalidated statutes that in the process of regulating the *methods* of abortion, imposed significant health risks." *Id.* (emphasis in original).

2. WHEN BANNING "PARTIAL-BIRTH ABORTION," CONGRESSIONAL FINDINGS THAT A HEALTH EXCEPTION IS UNNECESSARY ARE NOT ENTITLED TO DEFERENCE WHEN THOSE FINDINGS ARE UNREASONABLE AND NOT SUPPORTED BY SUBSTANTIAL EVIDENCE.

Mr. Ashcroft asserts that I must give binding "deference" to the legislative Findings made by Congress in

the law banning "partial-birth abortion."[111] In particular, he asserts that I must give the type of deference the Supreme Court gave to Congress in two cases dealing with the cable industry. *See Turner Broadcasting Sys. Inc. v. FCC*, 512 U.S. 622, 667, 114 S. Ct. 2445, 129 L. Ed. 2d 497 (1994) (plurality opinion) (regarding a First Amendment challenge to a law that required cable stations to carry the shows of local commercial and public broadcast stations, and despite congressional findings set forth in the law and three years of congressional hearings upon which those findings were based, the Court remanded the case to the district court for an evidentiary hearing because of the "paucity of evidence" and other "deficienc[ies] in [the] record") ("*Turner I*"); *Turner Broadcasting Sys. Inc. v. FCC*, 520 U.S. 180, 117 S. Ct. 1174, 137 L. Ed. 2d 369 (1997) (based upon the congressional record, as supplemented by the findings of the district court on remand, the entire record supported Congress' predictive judgment that the "must-carry" provisions of the law furthered important governmental interests and therefore the law did not violate the First Amendment) ("*Turner II*").

In those cases, the Court stated that when "reviewing the constitutionality of a [federal] statute, 'courts must accord substantial deference to the *predictive judgments* of Congress.'" *Turner II*, 520 U.S. at 195, 117 S. Ct. 1174 (quoting *Turner I*, 512 U.S. at 665, 114 S. Ct. 2445) (emphasis added). The Court went on to state that deference was due if the "legislative con-

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[111] In its Findings, Congress also states the deference it believes it is due. Not surprisingly, Mr. Ashcroft's argument tracks the position urged by Congress.

clusion was reasonable and supported by substantial evidence. . . ." *Id.* at 211, 117 S. Ct. 1174.

The Supreme Court's language about "substantial deference" in the *Turner* cases is explicitly related to "predictive judgments of Congress." *Id.* at 195, 117 S. Ct. 1174. That is, when Congress is predicting events, such as the impact of a particular cable regulation on the economy of a still-developing industry as compared to the impact of that same regulation on a related but better-developed industry, those estimates are entitled to unusual latitude "lest we infringe on traditional legislative authority" to make "predictive judgments when enacting nationwide regulatory policy." *Turner II*, 520 U.S. at 196, 117 S. Ct. 1174. Stated in simple terms: When the answer to the relevant question can only be a guess because the answer will turn on accurately predicting future facts, Congress, being an elected body, is most often the place to make that guess. Here, in contrast, the answers to the relevant questions require no prophesy.

Still further, sometimes, as is the obvious case here, Congress' fact-finding authority has the potential to redefine the meaning of the Constitution as articulated by the Court in prior cases, and thus effectively take from the Supreme Court the ability to say what the Constitution means. In such a situation, judicial deference to facts found by Congress is much reduced and sometimes eliminated entirely. *See, e.g., United States v. Morrison*, 529 U.S. 598, 614, 120 S. Ct. 1740, 146 L. Ed. 2d 658 (2000) (explicitly disregarding "numerous findings regarding the serious impact that gender-motivated violence has on victims and their families" when determining whether a particular activity substantially affected interstate commerce). *See also City of Boerne*

v. Flores, 521 U.S. 507, 536, 117 S. Ct. 2157, 138 L. Ed. 2d 624 (1997) (striking down the Religious Freedom Restoration Act, a law enacted pursuant to the enforcement powers of Congress under section 5 of the Fourteenth Amendment, that attempted to "overrule" a prior decision of the Supreme Court; stating "[w]hen the political branches of the Government act against the background of judicial interpretation of the Constitution already issued, it must be understood that in later cases and controversies the Court will treat its precedents with the respect due them under settled principles, including *stare decisis*, and contrary expectations must be disappointed.") (emphasis in original).

For these two reasons—because the fact-finding process engaged in by Congress in this case requires no "predictive" judgment and because the fact-finding process engaged in by Congress in this case is explicitly intended to undercut *Stenberg*-I conclude that the Findings of Congress are not due "substantial" deference when deciding whether the ban is constitutional. But this conclusion does not mean that I can ignore Congress.

As previously noted, the Supreme Court made it clear in *Stenberg* that the government was *not* required to "grant physicians 'unfettered discretion' in their selection of abortion methods." *Stenberg*, 530 U.S. at 938, 120 S. Ct. 2597. Since that is true, it must also be true that Congress has the power, subject to judicial review, to determine whether a health exception is necessary regarding the performance of a particular abortion procedure. And, if that premise is also correct, then Congress' factual judgments about "the selection of abortion methods" must, under certain circumstances, be entitled to binding deference. Otherwise, the power

possessed by Congress to limit a physician's exercise of unprincipled discretion in the selection of abortion methods becomes illusory.

Therefore, and shorn of the adjective "substantial," I believe the Findings of Congress are entitled to binding deference if the test (as opposed to the gloss) announced by the *Turner* line of cases is satisfied. Specifically, I conclude that the factual judgments of Congress when banning an abortion procedure are entitled to binding deference if "the legislative conclusion was reasonable and supported by substantial evidence . . . ." *Turner II*, 520 U.S. at 211, 117 S. Ct. 1174. In this regard, I am not "at liberty to substitute [my] judgment for the reasonable conclusion of a legislative body." *Id.* at 212, 117 S. Ct. 1174.

Nevertheless, simply because Congress has spoken does not mean that the court becomes a rubber stamp. As Justice Thomas has made clear when discussing the deference due congressional findings in another context, if Congress "could make a statute constitutional simply by 'finding' that black is white or freedom, slavery, judicial review would be an elaborate farce." *Lamprecht v. FCC*, 958 F.2d 382, 392 n.2 (D.C. Cir. 1992) (the Court of Appeals, with Justice Thomas sitting as Circuit Justice, held that a governmental preference for female radio station owners violated equal protection principles). Thus, a deferential standard of review must never be allowed to convert judicial review of congressional fact-finding into an "elaborate farce."

Indeed, the *Turner* cases require that I closely examine the congressional record to determine its adequacy to support the factual findings reached by Congress. *Turner I*, 512 U.S. at 664, 667, 114 S. Ct. 2445

(despite three years of congressional hearings and resultant congressional findings, there was a "paucity of evidence" and "deficienc[ies] in" that record requiring the government to prove at an evidentiary hearing before the district court that the "recited harms are real" and the law "will in fact alleviate these harms in a direct and material way"). For afficionados of "levels of scrutiny," Justice Breyer has described the *Turner* standard as "heightened, not 'strict' scrutiny," *United States v. American Library Ass'n, Inc.*, 539 U.S. 194, 217, 123 S. Ct. 2297, 156 L. Ed. 2d 221 (2003) (Breyer, J., concurring) and Justice Souter has described the standard as involving "intermediate scrutiny." *City of Erie v. Pap's A.M.*, 529 U.S. 277, 311, 120 S. Ct. 1382, 146 L. Ed. 2d 265 (2000) (Souter, J., concurring and dissenting.[112]

I may also take additional evidence to decide the reasonableness of the congressional fact finding. *Turner II*, 520 U.S. at 196, 117 S. Ct. 1174 (to ascertain whether a "substantial basis" exists to "support Congress' conclusion[,]" the Supreme Court would consider "first the evidence before Congress and then the further evidence presented to the district court on remand to supplement the congressional determination"). In fact, the weakness of the congressional record in *Turner I* caused the Supreme Court to remand and require an evidentiary hearing where the government had the burden of persuasion. *Turner I*, 512 U.S. at 667-68, 114 S. Ct. 2445.

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[112] According to Justice Souter, the Supreme Court's "cases do not identify with any specificity a particular quantum of evidence" that must exist in order to sustain a legislative enactment subject to *Turner*-like review. *City of Erie*, 529 U.S. at 311, 120 S. Ct. 1382.

Most importantly, stating this abstract approach to deference is only the beginning and not the end of the inquiry. Generalized standards of review are never meaningful until they are applied to the substantive law. Here the substantive law is set forth in *Stenberg*, and the primary holding of that decision states: "[W]here substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women's health," the Constitution "requires the statute to include a health exception when the procedure is "'necessary, in appropriate medical judgment, for the preservation of the . . . health of the mother."'" *Stenberg*, 530 U.S. at 938, 120 S. Ct. 2597 (quoting *Casey*, 505 U.S. at 879, 112 S. Ct. 2791, in turn quoting *Roe v. Wade*, 410 U.S. at 164-65, 93 S. Ct. 705).

In other words, where a plaintiff-doctor presents some evidence showing a need for a particular surgical procedure, the burden of persuasion rests upon the *government* (Congress) to "convince[ ] us that a health exception is never necessary to preserve the health of women."[113] *Id.* at 937-38, 120 S. Ct. 2597 (internal quotation marks omitted). Colloquially, if the evidence is no more than evenly balanced, a "tie" goes to the health of women and not to the fetus. This is the substantive law to which the *Turner* standard of review applies.

Therefore, applying the *Turner* standard of review to the *Stenberg* substantive legal principle, the case-deciding question may be properly stated as follows: Is there substantial evidence in the relevant record from

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[113] However, and as discussed more fully later, if the plaintiff-doctor's evidence relates only to previability abortions, then the court should limit its decision accordingly.

which a reasonable person could conclude that there is *no substantial medical authority* supporting the proposition that banning "partial-birth abortions" could endanger women's health? One might also phrase that question this way: Is there substantial evidence in the relevant record from which a reasonable person could conclude that the banned procedure is *never necessary, in appropriate medical judgment*, for the preservation of the health of the woman? Remembering always the legal obligation of Congress and the courts to "tolerate responsible differences of medical opinion," *Stenberg*, 530 U.S. at 937, 120 S. Ct. 2597, I respectfully answer these questions in the negative.

3. THE CONGRESSIONAL RECORD PROVES THAT THERE IS A SUBSTANTIAL BODY OF MEDICAL OPINION SUPPORTING USE OF THE BANNED PROCEDURE TO PRESERVE THE HEALTH OF WOMEN AND THERE IS NO CONTRARY "CONSENSUS."

The first Congressional Finding states that a "medical . . . *consensus* exists that the practice of performing a partial-birth abortion . . . is never medically necessary and should be prohibited." Congressional Finding (1), Pub. L. No. 108-105, § 2, 117 Stat. 1201 (2003) (emphasis added). In the same vein, Congress also found that the banned procedure was "outside the standard of medical care." *Id.* at Finding (13). However, this conclusion is contradicted by the record that Congress gathered. In fact, there was no evident consensus in the record that Congress compiled. There was, however, a substantial body of medical opinion presented to Congress in opposition. If anything, and assuming reliance upon physicians with experience in surgical abortions is appropriate, the congressional re-

cord establishes that there was a "consensus" in favor of the banned procedure.

For example,

* Opposition to the ban and support for the banned procedure in certain circumstances came from nearly half (22 out of 46) of all individual physicians who expressed non-conclusory opinions to Congress. (*See* Appendix II to this opinion.[114]) If one only counts doctors who claimed to practice obstetrics and gynecology, including the performance of abortions, more than half (19 out of 37) of those physicians opposed the ban and supported the banned procedure in certain circumstances. (*See* Appendix II to this opinion.[115])

* Opposition to the ban and support for the banned procedure in certain circumstances came from board-certified obstetricians and gynecologists.

* Opposition to the ban and support for the banned procedure in certain circumstances came from professors of obstetrics and gynecology (including two chairs of departments) at such medical schools as Johns Hopkins; Washington University; the University of Illinois; Cornell University; Albert Einstein; University of California; New Jersey; and Columbia University.

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[114] Of the 47 physicians listed in Appendix II, one physician, testifying about anesthesiology, remained neutral.

[115] Drs. Haskell, Robinson, McMahon, Campbell, Hern, Schrieber, Cromer, Burd, Scommegna, Sherline, Edwin, Rashbaum, Jones, Grimes, Roche, Weiss, Darney, Cullins, and Davis.

* Opposition to the ban and support for the banned procedure in certain circumstances came from physicians practicing in the obstetrics and gynecology departments at major metropolitan hospitals in New York, Chicago, and San Francisco.

* Opposition to the ban and support for the banned procedure in certain circumstances came from ACOG, the nation's leading medical association concerned with obstetrics and gynecology.

Based upon its own record, it was unreasonable to find, as Congress did, that there was "consensus" of medical opinion supporting the ban. Indeed, a properly respectful review of that record shows that a substantial body of contrary, responsible medical opinion was presented to Congress. A reasonable person could not conclude otherwise.

4. THE CONGRESSIONAL RECORD CONTRADICTS THE MAIN CONGRESSIONAL FINDINGS[116] REGARDING THE NEED FOR AND SAFETY OF THE BANNED PROCEDURE AND ESTABLISHES THAT USE OF THE BANNED PROCEDURE IS NECESSARY TO PRESERVE THE HEALTH OF WOMEN UNDER CERTAIN CIRCUMSTANCES. IN PARTICULAR, "PARTIAL-BIRTH ABORTIONS" PROVIDE WOMEN WITH SIGNIFICANT HEALTH BENEFITS IN CERTAIN CIRCUMSTANCES.

The critical Findings by Congress—such as that the banned procedure "poses serious risks to the . . .

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[116] Many of the subsidiary Findings of Congress are incorrect as well. However, no good purpose would be served by pointing them out.

health of a woman" undergoing the procedures[117] that there is "no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures,"[118] and that the banned procedure "is never necessary to preserve the health of a woman"[119]—are unreasonable and not supported by substantial evidence in the congressional record. Again, the congressional record disproves the Congressional Findings.

For example,

* Of the 11 doctors who presented information to Congress and who clearly appeared to have recent surgical abortion experience, 10[120] of them opposed the ban. Even the one dissenter[121] acknowledged that he had used, and would use, the banned procedure to save the life of a woman. Thus, 91% of the doctors with relevant experience in performing abortions opposed the ban.

* Of the eight doctors who presented information to Congress and who had actually used the banned procedure, or some variant of it, seven of them opposed the ban, finding the procedure to be either the best and safest in certain circumstances or possibly so.[122] (As noted, the dissenter[123] used

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[117] Congressional Findings (2) & (14)(A), Pub. L. No. 108-105, § 2, 117 Stat. 1201 (2003).

[118] *Id.* at Finding (14)(B).

[119] *Id.* at Finding (13).

[120] Drs. Haskell, Robinson, McMahon, Campbell, Hern, Rashbaum, Jones, Grimes, Darney, and Cullins.

[121] Dr. Calvin.

[122] Drs. Haskell, McMahon, Hern, Rashbaum, Jones, Grimes, and Darney.

the procedure in life-threatening emergencies.) Of these seven doctors, at least two are board-certified in obstetrics and gynecology,[124] one has been routinely performing and teaching the procedure as a professor of obstetrics and gynecology at Cornell University since 1979,[125] one is the author of a leading textbook on abortion,[126] and another[127] is the chief of obstetrics and gynecology at a major metropolitan hospital where a large number of abortions are performed. The other two[128] performed the procedure thousands of times with very low complication rates and they reported the results of their surgeries in detailed papers presented to peers who performed abortions. Thus, 100% of the doctors who used the banned procedure or some variant believed that it was necessary and safe in some circumstances, and 88% of those same doctors opposed the ban's lack of a health exception.

* When challenged by one Senator to provide specific examples of the need for the banned procedure to preserve the physical health of a woman, another Senator presented the statement of Dr. Philip Darney. Darney provided two very specific and detailed examples. He said: "These two patients provide examples from my memory of situations in which the 'intact D & E' technique

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[123] Dr. Calvin.

[124] Drs. Jones and Grimes.

[125] Dr. Rashbaum.

[126] Dr. Hern.

[127] Dr. Darney.

[128] Drs. Haskell and McMahon.

was critical to providing optimal care. I am certain that a review of our hospital records would identify cases of sever [sic] pre-eclampsia, for example, in which 'intact D & E' was the safest technique of pregnancy termination." (Court's Ex. 9, at 101.) Mindful that one of the ban's supporters[120] praised Dr. Darney's "broad experience with surgical abortion" (*id.* at 109), Congress did not seriously pursue Dr. Darney's specific explanation. Indeed, only one doctor who claimed to have any experience performing abortions (Dr. Calvin, who "rarely" did so and who used the banned procedure himself to save the life of a woman) disagreed with Dr. Darney, and that doctor disagreed with Dr. Darney only after acknowledging that the cases described by Dr. Darney "are certainly complicated." (*Id.* at 105.) The remainder of the doctors who disagreed with Dr. Darney claimed to have no experience performing surgical abortions. Thus, when Congress asked for, and was provided with, detailed and specific examples of the need for, and safety of, the banned procedure to preserve the physical health of women from a highly qualified and very experienced doctor who performed abortions to protect the health of women, it failed to make a diligent inquiry and instead elected to accept the contrary views of the inexperienced.

* While Congress relied upon part of the statements from the AMA, Congress ignored a critical qualification in the AMA's scientific report on this subject. That is, when the AMA's scientific panel

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[120] Dr. Goodwin.

recommended against use of the procedure, it qualified that proviso with this caveat: "unless alternative procedures pose materially greater risk to the woman." (Ct.'s Ex. 8, at 203.) Then the AMA emphasized that a "physician, must, however, retain the discretion to make that judgment, acting within standards of good medical practice and in the best interest of the patient." (*Id.*)

* ACOG, the nation's leading medical organization in the field of obstetrics and gynecology, told Congress several times that the procedure should not be banned. In part this was because "[w]hen abortion is performed after 16 weeks, intact D & X is one method of terminating a pregnancy" and that procedure "may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman . . . ." (Ct.'s Ex. 8, at 231-32.) In fact, Stanley Zinberg, M.D., Vice President of Clinical Practice Activities of ACOG, told the Senate that "there are rare occasions when Intact D & X is the most appropriate procedure" and "[i]n these instances, it is medically necessary." (Def.'s Ex. 897, at S12982.)

The long and short of it is that Congress arbitrarily relied upon the opinions of doctors who claimed to have no (or very little) recent and relevant experience with surgical abortions, and disregarded the views of doctors who had significant and relevant experience with those procedures. It is unreasonable to ignore the voices of the most experienced doctors and pretend that they do not exist.

A fetal and maternal specialist (like Dr. Cook) who has never, or very infrequently, performed a surgical

abortion of a live fetus, can only speculate about the real health risks of surgical abortion. The views of such inexperienced doctors have little value when compared to the opinions of surgeons who are experienced abortionists.[130] Relying upon experienced surgeons, with specific clinical experience in the technique under discussion, is the reasonable and customary practice for those in the medical profession.

For example, in a non-political setting, Mr. Frist, the Senate Majority leader, and a highly regarded heart surgeon, has indicated that reliance upon "very experienced surgeons" with "vast clinical experience" in the specific "technique" is appropriate. *See* William H. Frist, M.D. & D. Craig Miller, M.D., *Repair of Ascending Aortic Aneurysms and Dissections*, J. Cardiac Surg. 33, 45-46 (March 1986) (discussing "composite operative techniques" and stating, "For these reasons, certain very experienced surgeons and authorities in this field have abandoned the 'graft inclusion' or (Bentall) wrapping technique. On the basis of his vast clinical experience, Crawford now prefers to perform the coronary anastomosis[131] and distal aortic anastomosis using full-thickness end-to-side suture lines (similar to the methods illustrated herein) and not to wrap the

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[130] I do not use the term "abortionist" pejoratively. So long as abortion is legal, doctors who perform abortions and who properly concentrate on the health of their female patients will be treated in this court with the same high degree of respect as fetal and maternal specialists who do not perform abortions and who properly divide their loyalties between the health of the fetus and the health of its mother.

[131] In this sense, "anastomosis" means "[a]n operative union of two structures (*e.g.*, vessels . . .)." *Stedman's Medical Dictionary* 70 (27th ed. 2000).

completed repair with the residual aneurysm sac."[132]) (citations omitted).

In summary, the congressional record proves that the key Congressional Findings are unreasonable. The inferences that Congress drew from its record are not supported by substantial evidence contained within that record. In fact, the congressional record proves the opposite of the Congressional Findings. According to responsible medical opinion, there are times when the banned procedure is medically necessary to preserve the health of a woman and a respectful reading of the congressional record proves that point. No reasonable and unbiased person could come to a different conclusion.

5. THE TRIAL RECORD CONFIRMS THAT THERE IS A SUBSTANTIAL BODY OF MEDICAL OPINION SUPPORTING USE OF THE BANNED PROCEDURE TO PRESERVE THE HEALTH OF WOMEN AND THERE IS NO CONTRARY "CONSENSUS."

Aware that the Supreme Court's abortion jurisprudence, as it regards the need for specific types of abortion procedures, "tolerate[s] responsible differences of medical opinion[,]" *Stenberg*, 530 U.S. at 937, 120 S. Ct. 2597, Congress found that partial-birth abortions were never medically necessary and that such a conclusion was accepted by the medical community.[133] As I have

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[132] Incidentally, Dr. Frist cites no peer-reviewed studies when lauding Crawford's technique. Apparently, Crawford's "vast clinical experience" was sufficient.

[133] Congressional Findings (1) & (13), Pub. L. No. 108-105, § 2, 117 Stat. 1201 (2003) (a "medical . . . consensus exists" that the banned procedure "is never medically necessary and should be prohibited"; the banned procedure "lies outside the standard of medical care").

earlier indicated, the record Congress itself compiled disproves this assertion. As I shall next describe, the trial record also flatly contradicts that Finding.

Ignoring the plaintiffs' presentation for a moment, the evidence presented at trial by Mr. Ashcroft disproves Congress's Finding that a medical consensus agrees that partial-birth abortions are never necessary. Three examples illustrate the point:

* Dr. Watson Bowes, a supporter of the ban, who was described in the congressional record as "an internationally recognized authority" (Ct.'s Ex. 4, at 107), agreed that "there is no consensus in the medical community that an intact D & X is never medically necessary." (Tr. 963.) On the contrary, he testified that there was a "body of medical opinion" consisting of the "position taken by the American College of Obstetrics and Gynecologists" and "a responsible group of physicians practicing at a variety of hospitals and teaching at a variety of medical schools" that "an intact D & E may be the safest abortion procedure for some women in some circumstances." (Tr. 962-63).[134]

* Dr. Elizabeth Shadigian, a full-time faculty member at the University of Michigan in obstetrics and gynecology, testified for the government. She admitted that the chair of her department, Dr. Timothy R.B. Johnson, was a

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[134] Although Dr. Bowes provided Congress with information supportive of the ban, he was not consulted about the specific Findings. Therefore, Dr. Bowes did not believe that Congress was aware that he disagreed with some of the Act's significant Findings at the time the ban was passed. (Tr. 992-94.)

"plaintiff in the New York case challenging the partial-birth abortion ban"; that having known Dr. Johnson for 20 years she respected him as a physician; and that Dr. Johnson and Dr. Shadigian disagreed on this issue. (Tr. 1561 & 1591.) Moreover, during the 17th week of gestation, before many physicians are comfortable inducing fetal death by injection, Dr. Shadigian also admitted that it would be consistent with the standard of care at the University of Michigan to crush the skull of a living fetus when the body was delivered intact outside the cervix and into the vaginal cavity if the skull was trapped by the cervix and the woman was hemorrhaging. (Tr. 1598-1602.)

* Dr. Charles Lockwood, the Chair of the Department of Obstetrics and Gynecology at Yale, testified for the government (Tr. 1639-40) to provide "objective . . . data" (Tr. 1647), although he was not an "advocate of the" ban[135] and was "enraged" by certain portions of it. (Tr. 1731-32.) Among many other things, Dr. Lockwood testified that: (1) when he was the Chair of the Obstetrics and Gynecology Department at New York University (N.Y.U.), he hired a physician who performed intact D & E procedures (Tr. 1744); (2) during his last year at NYU, between 75 to 100 second-trimester intact D & E procedures were performed, and, although he was not specifically aware that those procedures were being conducted, he would have allowed those

[135] I found Dr. Lockwood extremely credible particularly because he was unusually candid.

intact D & E procedures to be performed had he known of them (Tr. 1745 & 1764); and (3) in his opinion there are "compelling enough arguments as to [the banned technique's] safety, that I certainly would not want to prohibit its use in my institution." (Tr. 1706 & 1763 (statement on direct examination, affirmed on cross-examination).)

The plaintiffs' trial evidence also disproves Congress' Finding that a medical consensus exists that partial-birth abortions are never necessary. Once again, several examples from the plaintiffs' evidence prove that, if anything, a medical consensus of physicians experienced in surgical abortions favors the banned procedure, to wit:

* From California, Dr. Maureen Paul, a board-certified physician in obstetrics and gynecology, who holds a master's degree in epidemiology, testified in opposition to the ban. She was the editor-in-chief of the 1999 publication, *A Clinician's Guide to Medical and Surgical Abortion*,[136] which is one of the standard reference guides on abortion care. (Pls.' Ex. 125, at 11-12.) Dr. Paul has experience with all types of abortion, including the banned procedure; she serves as the Director of Training at the University of California San Francisco Center for Reproductive Health Research and Policy; and she teaches

[136] In this record the *Guide* may be found as Pls.' Ex. 70. Chapter 10 of the *Guide* is entitled "Surgical Abortion After the First Trimester." That chapter is authored by W. Martin Haskell, Thomas R. Easterling, and E. Steve Lichtenburg. In Chapter 10, the authors extensively discuss the banned procedure.

abortion techniques to residents and medical care providers. In addition, she hires and supervises physicians at eight medical clinics run by Planned Parenthood where a wide range of medicine is practiced including abortions up to 18 weeks 6 days of pregnancy. (Pls.' Ex. 125, at 6-9; Pls.' Ex. 125A.) Based upon this experience, Dr. Paul believes that, while the standard D & E is safe, the intact D & E is safer. (Pls.' Ex. 125, at 102-03.)

* From New York, Dr. Carolyn Westhoff, who holds a medical degree from the University of Michigan, subsequently studied epidemiology at the London School of Hygiene and Tropical Medicine, and was a post-doctoral fellow at Oxford University in epidemiology, testified against the ban. (Pls.' Ex. 126, at 737-38; Pls.' Ex. 126A.) She is a board-certified obstetrician and gynecologist and holds a joint professorship at Columbia University in obstetrics and gynecology in the College of Physicians and Surgeons and in epidemiology, population, and family health in the School of Public Health. (Pls.' Ex. 126A.) She teaches and supervises medical students and residents and is experienced with all forms of abortions including the intact version. She testified that the intact D & E procedure has been taught for the last five or six years as a part of the fellowship program in family planning at her institution (Pls.' Ex. 126, at 748-51), and is taught at various other medical schools such as Albert Einstein, NYU, Cornell University, Northwestern, and the University of California at San Francisco. (Pls.' Ex. 126, at 897-98.) Dr. West-

hoff holds the view that the intact D & E is safer than the dismemberment D & E because there are less instrument passes, fewer bony fragments, and a reduced likelihood of retaining fetal parts in the uterus. (Pls.' Ex. 126, at 824-25.) In her opinion, Congress was wrong in finding that the intact D & E is not an accepted medical practice. (Pls.' Ex. 126, at 901.)

* From Chicago, Dr. Cassing Hammond, who is board-certified in obstetrics and gynecology, a diplomate of the National Board of Medical Examiners, and an assistant professor at Northwestern University's Department of Obstetrics and Gynecology, testified against the ban. (Pls.' Ex. 124A.) He is very experienced with both medical and surgical methods of abortions from early in gestation through 24 weeks. Understanding that he supervises Northwestern's two-year fellowship program in family planning and contraceptive research, which includes teaching abortion procedures; that he has been performing abortions for 15 years (Pls.' Ex. 124, at 520, 522, 526-27); and that he routinely performs intact D & E abortions (Pls.' Ex. 124, at 533 & 675), including occasional conversions of fetuses to the breech position (Pls.' Ex. 124, at 686), Dr. Hammond testified that: (1) Congress was incorrect in finding that the intact D & E is never necessary to preserve the health of the woman and violates the standard of care; and (2) since Dr. Hammond has been doing D & E abortions, or for the last 15 years, the standard of care has been to remove the fetus as intact as possible. (Pls.' Ex. 124, at 608-09.)

If one looks at the trial evidence in the aggregate, the same thing is true. The purported consensus in favor of the ban does not exist:

* Overall, 19 physicians testified[137] in this case who personally had some post-internship experience (no matter how minimal) with pregnancy termination.[138] Of those 19 physicians, one of the government's witnesses[139] agreed that there was no medical consensus supporting the ban, another[140] agreed that the safety of the procedure had been sufficiently shown such that he would not want the procedure banned in his institution, and a third government witnesses[141] admitted that use of the procedure was within the standard of care under certain circumstances. Of the remaining 16 doctors, only 3 thought the ban was appropriate.[142]

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[137] This number includes doctors who testified live in this case, who testified in the New York or California cases, or who testified by deposition. By stipulation, the parties agreed that some of the trial testimony from the New York and California cases would be considered as evidence in this case, and that certain depositions would also be considered as trial evidence here.

[138] *See* Appendix III. Those physicians were: Dr. Carhart, Dr. Fitzhugh, Dr. Vibhakar, Dr. Knorr, Dr. Bowes, Dr. Sprang, Dr. Cook, Dr. Shadigian, Dr. Lockwood, Dr. Doe, Dr. Chasen, Dr. Broekhuizen, Dr. Frederiksen, Dr. Creinin, Dr. Westhoff, Dr. Paul, Dr. Clark, Dr. Hammond, and Dr. Cain.

[139] Dr. Bowes.

[140] Dr. Lockwood.

[141] Dr. Shadigian.

[142] Those three were Dr. Sprang, Dr. Cook, and Dr. Clark. They had very little experience with surgical abortions generally, and

* Thus, out of 19 doctors who provided sworn testimony in this case and who personally had some post-internship experience with pregnancy terminations, 16 of them (84%) opposed the ban outright, agreed that there was no medical consensus in favor of the ban, agreed that the safety of the procedure had been sufficiently shown such that he would not want the procedure banned in his institution, or conceded that the banned procedure was within the standard of care under certain conditions.

In summary, I find and conclude from the trial evidence that Congress' Finding—that a medical consensus supports the ban because partial-birth abortions are unnecessary—is both unreasonable and not supported by substantial evidence. Congress was plainly mistaken.

6. THE TRIAL RECORD CONTRADICTS THE MAIN CONGRESSIONAL FINDINGS REGARDING THE NEED FOR AND SAFETY OF THE BANNED PROCEDURE AND ESTABLISHES THAT USE OF THE BANNED PROCEDURE IS NECESSARY TO PRESERVE THE HEALTH OF WOMEN UNDER CERTAIN CIRCUMSTANCES. IN PARTICULAR, "PARTIAL-BIRTH ABORTIONS" PROVIDE WOMEN WITH SIGNIFICANT HEALTH BENEFITS.

Emphasizing, again, that the Constitution protects, and Congress has the legal obligation to accept, "responsible differences of medical opinion" regarding the need for specific types of abortion procedures, *Stenberg*, 530 U.S. at 937, 120 S. Ct. 2597, the trial evidence es-

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very little experience with D & E abortions specifically. They had no experience with the banned procedure.

tablishes that a large and eminent body of medical opinion believes that partial-birth abortions provide women with significant health benefits in certain circumstances. In particular, the trial evidence shows that Congress was wrong, and unreasonably so, when it found that the banned procedure "poses serious risks to the . . . health of women,"[143] that there is "no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures,"[144] and that the banned procedure is "never necessary to preserve the health of a woman."[145]

It is worth remembering that an enormous amount of time has already been spent on this issue by federal trial judges throughout this country. Those judges have heard and carefully considered the need for and safety of the banned procedure. In *Stenberg*, the Supreme Court observed that this court had found that a "partial-birth abortion" (as defined by Nebraska) "'may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman,'" and, "[w]ith one exception, the [eight other] federal trial courts that have heard expert evidence on the matter have reached similar factual conclusions." 530 U.S. at 932, 120 S. Ct. 2597 (quoting ACOG Statement) (citations to cases omitted).

In 2004, two more federal trial courts have specifically found that "partial-birth abortions" are safe and sometimes necessary to preserve the health of women. See *Planned Parenthood Fed'n of Am.* v. *Ashcroft*, 320

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[143] Congressional Findings (2) & (14)(A), Pub. L. No. 108-105, § 2, 117 Stat. 1201 (2003).

[144] *Id.* at Finding (14)(B).

[145] *Id.* at Finding (13).

F. Supp. 2d 957, 1033 (N.D. Cal. 2004) ("[T]he record before this court, like the district court's record in *Stenberg*, demonstrates that 'significant medical authority supports the proposition that in some circumstances, [intact D & E] is the safest procedure.' *Stenberg*, 530 U.S. at 932, 120 S. Ct. 2597. These include the following considerations, present also in the *Stenberg* case, that among other maternal and fetal conditions for some women, other abortion procedures present 'a larger than necessary risk' of: ['](1) a longer operating time; (2) greater blood loss and infection; (3) complications from bony fragments; (4) instrument-inflicted damage to the uterus and cervix; (5) exposure to the most common causes of maternal mortality (DIC and amniotic fluid embolus); [and] (6) complications arising from retained fetal parts.[']") (quoting *Carhart* v. *Stenberg*, 11 F. Supp. 2d 1099, 1127 (D. Neb. 1998) (also considering Partial-Birth Abortion Ban Act of 2003)); *Richmond Med. Ctr.* v. *Hicks*, 301 F. Supp. 2d 499, 514 (E.D. Va. 2004) (considering Virginia law) ("There is substantial medical authority, including testimony from defendants' experts, that supports the proposition that banning D & E's, and the manner in which Dr. Fitzhugh[146] performs D & E's, including intact D & E's, could endanger women's health. Through testimony and declaration, Dr. Fitzhugh and Dr. deProsse have stated that the manner in which Dr. Fitzhugh performs D & E's that are prohibited by the Act is both the safest and most medically appropriate for some of his patients and have relied on their experience and additional medical authority in forming those opinions.").

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[146] Of course, Dr. Fitzhugh is also a plaintiff in this case.

While not deciding for himself whether the banned procedure was safe, Judge Casey recently declared the Partial-Birth Abortion Ban Act of 2003 was unconstitutional as it lacked a health exception. *National Abortion Federation* v. *Ashcroft*, 330 F. Supp. 2d 436 (S.D.N.Y. 2004). In his view, Congress acted unreasonably in omitting such an exception given the evidence. In particular, he found that both the congressional record and the trial record demonstrated that a significant body of medical opinion "supports the notion that D & X offers some safety advantages." *Id.* at 853, 2004 WL 1906165 at *49.

In short, the vast majority of federal trial courts to carefully weigh the evidence on this question have found that the procedure is safe and medically necessary. While those opinions are no substitute for my independent judgment of the evidence in this case, they provide a measure against which to test both the validity and objectivity of my decision.

With this important context firmly in mind, I find and conclude that the overwhelming weight of the trial evidence proves that the banned procedure is safe and medically necessary in order to preserve the health of women under certain circumstances. In the absence of an exception for the health of a woman, banning the procedure constitutes a significant health hazard to women. Such a ban is therefore an undue burden. In the same vein, I also find and conclude that Mr. Ashcroft, who bears the burden of persuasion, has failed to present substantial evidence to the contrary. Given the tolerance for responsible differences of medical opinion required by the substantive law, no reasonable person could come to different conclusions.

In particular, I decide that:

1. Childbirth is more dangerous to the health of women than abortion.

2. Congress's Finding that the banned procedure is dangerous to the health of women is not supported by competent medical evidence and is based upon speculation.

3. The D & E method is the "gold standard" for previability abortions from early in the second trimester through 24 weeks; it is the most common method of abortion during this time and it is safer than induction abortions through approximately 20 weeks. While induction abortions are roughly comparable in relative safety to D & E abortions after 20 weeks, induction abortions are not available to many women because hospitals refuse to perform them; induction abortions are absolutely or relatively contraindicated for some women; and induction abortions in hospitals typically take more time, involve more expense, and are more painful to women than D & E abortions. Hysterotomies or hysterectomies are much more dangerous both in terms of mortality and morbidity than either D & E or induction abortions during the second trimester.

4. The intact D & E or D & X (the banned procedure) is merely a variant of the standard D & E.

5. In the hands of surgeons with experience using it, the banned procedure is, sometimes, the safest abortion procedure to preserve the health of women. Oversimplified, this is because: (a) the intact procedure reduces the need for placing forceps into the uterus thus reducing the risk of

trauma to the uterus and the cervix; (b) the intact procedure reduces the possibility of retaining fetal parts or fluids in the uterus and retention of fetal parts or fluids can cause death or serious illness; (c) removal of the intact fetus reduces the possibility of exposing maternal tissues to sharp bony fragments stemming from the dismemberment of the fetus; and (d) the intact procedure is faster than the standard D & E, thus reducing the time and expense of the operation, the risk of hemorrhage, and the risk of complications from anesthesia.[147] These significant safety advantages are particularly evident when the fetus does not require manual conversion in order to complete the intact procedure. In these general circumstances, the benefits of the procedure to these women are significant.

6. In the hands of surgeons with experience using it, the banned procedure is the safest abortion procedure to preserve the health of women in special cases. For example, the banned procedure is the safest in the case of cancer of the placenta most often diagnosed in the second trimester and associated with severe preeclampsia, where instrumentation of the uterine wall should be avoided as much as possible. Another example is where a woman, who is between 20 and 24

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[147] These are the same findings that I made in Dr. Carhart's suit against Nebraska and which the Supreme Court found to have been "highly plausible" and "record-based." *Stenberg*, 530 U.S. at 936, 120 S. Ct. 2597. The evidence presented to me in this case more strongly supports my earlier factual findings about the need for and safety of "partial-birth abortions" to preserve the health of women when the fetus is nonviable.

weeks pregnant, suffers from a complete placenta previa and where an induction abortion is always contraindicated. In these special cases, and others, the benefits of the banned procedure to women are significant.

a. THE TRIAL EVIDENCE PROVES THAT CONGRESS ERRED WHEN IT FOUND THE BANNED PROCEDURE POSES SERIOUS RISK TO THE HEALTH OF WOMEN.

Congress tried to turn the *Stenberg* decision on its head. Contrary to the findings of numerous federal trial courts throughout the nation, Congress asserted that "partial-birth abortions" are dangerous to the health of women. The trial evidence in this case proves that Congress grievously erred when it made that finding.

When objectively trying to assess the danger of abortion procedures, one must start with childbirth. That is, absent an abortion, what are the risks of childbirth? In general, childbirth is more dangerous than abortion, particularly when the fetus is not viable and when the woman is older. As Dr. Maureen Paul-a board-certified obstetrician and gynecologist, an expert in abortion, and an epidemiologist—put it, abortion is "hands down" a safer option than carrying a pregnancy to term. (Pls.' Ex. 125, at 38.) Thus, any assertion that a particular abortion method is risky must be judged against the generally more dangerous alternative of childbirth.

That said, in the gestational age ranges we speak of in this case, there are three broad choices for abortion. They are: (1) the method involving vaginal surgery typified by the D & E abortion; (2) the method, using

drugs, which mimics childbirth, commonly referred to as an induction abortion (sometimes called a medical abortion); and (3) the abdominal-surgery method, for example, a hysterotomy. Of these three, virtually everyone agrees that surgery of the abdomen is far more dangerous to both life and health than the other alternatives. That is why it accounts for only a tiny fraction (0.07%) of second-trimester abortions. (Pls.' Ex. 125, at 46-47 (Dr. Paul).) Consequently, when one tries to determine the risk of abortion during the relevant gestational ages, one must compare the risks of vaginal surgery (D & E abortions) versus the risks of mimicking childbirth (induction abortions).

But, before one directly compares the risks of the two procedures, one must first assess the frequency of use. Frequency of use tends to show the nationwide preferences of physicians, and, indirectly, their assessment of the comparative risks of the two procedures.

Based on data from the Centers for Disease Control, 95% of all second-trimester abortions at 16 to 20 weeks of gestation were performed by D & E, and after 20 weeks of gestation, 85% were performed by D & E. In these statistics, intact D & Es were included in the figures for D & Es more generally. (Pls.' Ex. 125, Test. Dr. Paul 47-49; Pls.' Ex. 32, at 32 (Table 18) (Morbidity and Mortality Weekly Report, prepared by the Centers for Disease Control and Prevention) (November 28, 2003).) Thus, the clear choice of doctors was the D & E as opposed to the induction method.

Aside from the inference of relative safety shown by the national preference for the D & E method, the clear choice of the D & E, as opposed to the induction method, is probably driven in part by the refusal of many hospitals to allow abortions to be performed in

their facilities. Moreover, since induction abortions typically involve more time, expense, and pain than D & E abortions, it is quite likely that most women prefer D & E abortions as a result. For example, when doctors recently tried to conduct a randomized trial between D & E abortions and induction abortions, they reportedly dropped the study because not enough women were willing to undergo induction. (Pls.' Ex. 44 (David A. Grimes, et al., *Mifespristone and misoprostol versus dilation and evacuation for midtrimester abortion: a pilot randomised controlled study*, 111 Brit. J. Obstet. & Gynecol. 148 (Feb. 2004) ("The trial was stopped at one year because of low enrolment. Of 47 women eligible for the trial, 29 (62%) declined participation, primarily because of a preference for D & E abortion. Among the 18 participants enrolled, nine were randomised to treatment with mifepristone-misoprostol and 9 to D & E. Compared with D & E, mifepristone-misoprostol abortion caused more pain and adverse events, although none was serious.")).)

Turning then to a more direct comparison, according to the literature, D & Es are generally believed to be safer than induction abortions during the entire second trimester. (*E.g.*, Pls.' Ex. 19 (Amy M. Autry, et al., *A comparison of medical induction and dilation and evacuation for second-trimester abortion*, 187 Am. J. Obstet. & Gynecol. 393 (Aug. 2002) (a retrospective study comparing complication rates of patients undergoing D & E or induction between 14 and 24 weeks of gestation found that the "overall complication rate was significantly lower" for patients undergoing D & E abortions and "[m]ore Laminaria was associated with a decreased risk of complications with surgical abortions.")).) Most of the experienced physicians in this

case would not, however, make this generalization for the entire second trimester.

For example, Dr. Lockwood, the Chief of Obstetrics at Yale and a government witness, stated that prior to 20 weeks "there seems reasonable evidence that D & Es are associated with fewer complications than medical [induction] abortions." (Tr. 1746.) Dr. Hammond, a very experienced professor at Northwestern, also indicated that the D & E procedure is likely the safest procedure through approximately 20 weeks. (Pls.' Ex. 124, at 541-42.) However, in the hands of physicians who are very experienced with both types of abortion, the risks of D & E and induction can become roughly comparable after approximately 20 weeks. Thus, Dr. Hammond, who has a great deal of experience with the D & E method, including the intact D & E variation, and who also has a great deal of experience with induction abortions, believes that the risks are roughly comparable after 20 weeks. (*Id.*) Dr. Lockwood agreed that "after 20 weeks, D & Es, *intact D & Es* and medical induction abortions are comparable in terms of safety . . . ." (Tr. 1747 (emphasis added).)

One must keep in mind that the banned procedure, whether one calls it an intact D & E or a D & X or some other name, is only a variant of the D & E. Appearing before me was the very knowledgeable board-certified physician and professor of medicine and the history of science at the University of Michigan, Joel D. Howell, M.D., Ph.D. He has lectured and published papers in peer-reviewed journals about the development of surgical techniques. Dr. Howell opined that: (1) the intact D & E "came about as a logical consequence of physicians doing the D & E procedure"; (2) the intact D & E procedure has developed "well within the bounds of cur-

rently accepted medical practice" and consistent with the "very typical pattern" of surgical development; and (3) the intact D & E is not a new surgical technique, but a variation thereof. (Tr. 465-66.)

Therefore, since the standard D & E is safe; since the standard D & E is safer than, or at least as safe as, induction abortions during the relevant gestational ages; and since the banned procedure is merely a variant of the safe D & E, it borders on ludicrous to assert that the banned procedure is dangerous. But there is much more.

In addition to the testimony in this case of the many board-certified physicians who stated that the banned procedure was not dangerous, but was as safe as, and sometimes safer than, standard D & E and induction abortions, the lack of dangerousness is supported by hard data. For example, Chapter 10 of *A Clinician's Guide to Medical and Surgical Abortion* examined the intact procedure and data on complications regarding the procedure. (Pls.' Ex. 70.)

As noted earlier, Dr. Paul was the editor-in-chief of the *Guide*. Other editors included Drs. E. Steve Lichtenburg, Lynn Borgatta, David A. Grimes, and Phillip Stubblefield. At the time the *Guide* was written, Lichtenburg was the Medical Director at the Albany Medical-Surgical Center. Borgatta was an associate professor in the Department of Obstetrics and Gynecology at the Boston University School of Medicine. Grimes was a clinical professor in the Department of Obstetrics and Gynecology at the University of North Carolina. Stubblefield was professor and Chair of the Department of Obstetrics and Gynecology at the Bos-

ton University School of Medicine.[148] Chapter 10 was written by Drs. W. Martin Haskell, Thomas R. Easterling, and E. Steve Lichtenburg.

The authors of Chapter 10 to the *Guide* wrote that the complication rates for the banned procedure showed that the procedure was very safe:

> The intact D & E procedure combines long-standing obstetrical practices for delivery of advanced, compromised pregnancies with modern techniques of cervical dilation. The aim of intact D & E is to minimize instrumentation within the uterine cavity and achieve vaginal delivery of an intact fetus. Intact D & E is used as a method of second trimester abortion and, in the case of compromised pregnancies, as a technique for third trimester terminations. Intactness allows unhampered evaluation of structural abnormalities and can be an aid to patients grieving a wanted pregnancy by providing the opportunity for a final act of bonding.
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> Generally, cervical dilation is accomplished with multiple, serial osmotic dilators over 2 days or more. The goal is to achieve sufficient dilation to extract the largest part of the fetus, the bitrochanteric diameter of the pelvis, which is approximately 75% of the biparietal diameter. Combinations of different types of osmotic dilator are typically used.
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> In 1995 McMahon presented a 13-year personal series of 1362 intact D & E cases.[149] Ninety-eight

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[148] Dr. Stubblefield appeared before me in *Stenberg*. He was very knowledgeable and very credible.

[149] That important paper, which Congress appears to have ignored, is found as Pls.' Ex. 64 (J.T. McMahon, *Intact D & E: The*

percent of these cases were performed at a licensed ambulatory surgical center. Only cases with serious fetal (n = 451) or maternal (n = 173) indications were done after 24-26 weeks' gestation. McMahon devised and refined exacting protocols for vertex and breech delivery to minimize the danger of cervical and uterine injury.

McMahon effected delivery only after achieving ample cervical dilation, and he used a minimum of instrument passes. For example, in vertex position, once the central nervous system (CNS) contents were evacuated using an auger-tipped trocar, he grasped the calvarium with forceps in a controlled manner and extracted the fetus. In breech presentation, he converted the lie to footling and delivered the fetus using a Mauriceau-Smellie-Veit maneuver as described above. Dilation was sufficient to enable most complex presentations to be converted digitally or with a version forceps to vertex or breech presentation. McMahon devised special instruments for the procedure, and he recorded case-by-case measurements of fetal and cervical dimensions to improve delivery intervals, odds of intact delivery, and safety.

Using CDC criteria, four patients in McMahon's series experienced major complications, for a rate of 2.94 per 1000 cases. Three patients required transfusion, two for DIC and one for hemorrhage during dilation. The fourth patient required hospitalization for subacute bacterial endocarditis diagnosed 2 weeks after abortion. This major complication rate

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First Decade, presented at the National Abortion Federation Conference (April 2, 1995)).

> is virtually identical to that of an earlier series of nonintact D & Es reported by Hern (3.0/1000 cases) despite the fact that nearly one-fourth of the cases in McMahon's series exceeded Hern's 25-week gestation limit. In addition, Haskell has performed more than 1500 intact D & Es at 20-26 weeks' gestation without a serious event. No patient in his series experienced hemorrhage requiring transfusion, cervical laceration, uterine perforation, or retained tissue; and no hospitalizations or laparotomies were required.

(*Id.* at 136-37.)

Harping on the fact that no "peer-reviewed" paper had examined the technique, past critics have relied upon the false premise that if a surgical variation is not in a journal article, it must be unsafe. Aside from the silliness of requiring every variation of a proven surgical technique to be "peer-reviewed," this argument was lost to Congress and Mr. Ashcroft when Dr. Chasen and his colleagues in the Department of Obstetrics and Gynecology at the Weill Medical College of Cornell University wrote a "peer-reviewed" journal article on the subject. (Pls.' Ex. 27, Stephen T. Chasen, et al., *Dilation and evacuation at >20 weeks: Comparison of Operative techniques*, 190 Am. J. Obstet. & Gynecol. 1180 (2004).)

In that article, 383 patients were studied who were undergoing surgical abortions after 20 weeks at the New York Weill-Cornell Medical Center from June 1996 to June 2003. The intact procedure was performed in 120 cases, and the standard D & E in 263 cases. All of the procedures were performed by two physicians who were skilled in both techniques. Institutional-review-board approval was obtained for the study.

There was "no difference in procedure time or estimated blood loss in the two groups." (*Id.* at 3.) Complications occurred in 19 cases and "with similar frequency in the two groups." (*Id.*) Follow-up indicated that after the procedure, 62 subsequent pregnancies occurred, and there were no second-trimester miscarriages. (*Id.*) Spontaneous preterm birth in these subsequent pregnancies occurred twice in the intact group and twice in the standard D & E group. While the percentage of preterm births in the intact group (2 of 17 or 11.8%) was greater than the standard D & E group (2 of 45 or 4.4%), the difference was not statistically significant because the numbers of spontaneous preterm births in both groups were so small. (*Id.*)

The authors came to two conclusions. First, despite the fact that the intact group presented at a greater gestational age thus suggesting an increased likelihood of complications, the complication rate for the surgeries were "similar between patients undergoing dilation and evacuation and intact dilation and extraction after 20 weeks' gestation." (*Id.* at 3 & 9.) Regarding subsequent pregnancies, the "outcomes are similar between the two groups." (*Id.* at 3.)

Realizing that this article dramatically defeats the argument that without a peer-reviewed journal article one can infer that a variation of a surgical technique is dangerous, Mr. Ashcroft spent an enormous amount of time trying either to disparage or qualify away this study. He was not successful. And this lack of success is best explained by Dr. Lockwood, Mr. Ashcroft's final witness:

> Well, the study essentially shows that they are remarkably similar in their outcomes. The procedure

> times were literally identical, and the blood loss was literally identical, and the occurrence of complications was virtually identical. I would say that to be fair to-if one can be fair to a procedure, to be fair to the intact D & X procedure, the D & X was generally done at a more advanced gestational age, which I have already testified, increases the risk of surgical abortions for sure at higher parity. That may have actually made it easier potentially, but might have increased the risk of perforation. And so, you know, and the cervix was obviously more dilated. I don't think that affects complications. So from that standpoint, then, *I think that one can conclude that it would be extraordinarily unlikely that these two procedures have markedly different occurrences in the rate of complications, short-term complications.*

(Tr. 1719-20 (emphasis added).)

When asked by Mr. Ashcroft's counsel whether the size of the study was "sufficient to draw meaningful conclusions," Dr. Lockwood responded this way:

> *Well, they are not trivial; 120 patients and 263 patients are certainly a very large study.* One that would—I think, prove to be a valid indicator of certain—this gets into some really complicated statistical stuff, but basically, there is something called power analysis to prove the absence of a finding is real. And for some procedures where we, you know, where we might be looking for a 50% increase or decrease in a complication or a procedure time or blood loss, you can be pretty comfortable that there is not anything of that magnitude going on here. Could there be a 5% difference, or 10% difference in bleeding, blood loss or procedure time, yes. That's not

> terribly important clinically. The study is obviously underpowered, doesn't have adequate numbers to rule out differences in grave complications; death, perforation, which would require many, many more patients than this. But *it gives us a good sense that the overall rate of standard complications, immediate short-term complications were very similar in the two groups.*

(Tr. 1719-21 (emphasis added).)

Still further, Dr. Lockwood, who has a particular interest in studying subsequent preterm births, indicated that the Chasen article would cause him to do further study on that issue. However, the number of preterm births in the Chasen study following use of the intact procedure was "not statistically significant" (Tr. 1721) and would not "make me prohibit [the banned procedure's] use . . . ." (Tr. 1722.) Indeed, and as I have earlier indicated, Dr. Lockwood thought that there are "compelling enough arguments as to [the banned technique's] safety, that I certainly would not want to prohibit its use in my institution." (Tr. 1706.)

With all the foregoing in mind, it is important to stress that other government witnesses besides Dr. Lockwood disagreed with Congress' adverse safety Finding. For example, with the exception of the possibility that intact D & E may cause more preterm births in subsequent pregnancies,[150] Dr. Clark testified that

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[150] Dr. Clark derived this single concern from reading Dr. Chasen's peer-reviewed journal article. As just noted, Dr. Lockwood testified that any inference in the Chasen article that the intact D & E procedure caused more preterm births was "not statistically significant." (Tr. 1721.) And, although he would certainly study the issue further, Dr. Lockwood would not put "an enormous

there is no medical evidence to support the risks identified by Congress. With that one exception, Dr. Clark said that any suggestion that the intact D & E is less safe than a standard D & E is "pure speculation" and has "no place in a scientific discussion." (Def.'s Ex. 891, Test. Dr. Clark 2421.)

Another of Mr. Ashcroft's witnesses, Dr. Bowes, testified in a similar fashion. He was not aware of any study or other scientific evidence which establishes that the intact D & E is less safe than the traditional D & E or an induction abortion or which establishes that the intact D & E is more dangerous to a woman than any other abortion method. In short, Dr. Bowes believes that it has not been "proven" that the intact D & E would be dangerous to women. (Tr. 953-57.)

In all of the medical testimony presented to me through live witnesses, trial transcripts, or depositions, the only witnesses who unequivocally testified that the banned procedure was dangerous to the health of women were Drs. Sprang and Cook. Their views do not constitute substantial evidence.

Although they are certainly good and dedicated physicians, I found that both Dr. Sprang and Dr. Cook were too rigid in their beliefs to be entirely credible. Two examples will illustrate my point. Despite the need for informed consent, Dr. Sprang testified that he would not even tell his patients about the option of doing a standard D & E abortion at 20 weeks. (Tr. 1213.) At 17 weeks and with the woman bleeding and the intact fetus's head trapped in the cervix, and despite the obvious concerns about cervical incompetence, Dr. Cook

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amount of weight on it" and he would not prohibit the use of the banned procedure out of a concern for prematurity. (Tr. 1721-22.)

testified that, as a last resort, he would cut the women's cervix rather than decompress the skull in order to deliver the nonviable fetus.[151] (Tr. 1462-63.)

More importantly, Drs. Cook and Sprang had little or no personal experience with the techniques of surgical abortion that were at issue in this case. For example, Dr. Sprang had performed only one abortion on a living fetus during an emergency hysterotomy, and Dr. Cook had never performed a D & E on a living fetus. Thus, their extreme views about the efficacy and danger of surgical techniques that they have seldom, if ever, performed are unconvincing. In this regard, and to be clear, both the law and common courtesy shield Dr. Sprang and Dr. Cook from criticism regarding their personal decisions not to perform abortions. On the other hand, Dr. Sprang and Dr. Cook (and Congress) are not entitled to use those personal choices, and concomitant lack of experience, as a sword.

In summary, there is no factual basis, that is, no "substantial evidence," in the parlance of *Turner*, for Congress' Finding that the banned procedure is dangerous to the health of women. In fact, the opposite is true.

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[151] Dr. Cook's answer can profitably be compared with the answer to a similar question given by another government witness, Dr. Shadigian. She told me that it would be consistent with the standard of care at the University of Michigan to collapse the skull in this circumstance. (Tr. 1601-02.) It is also interesting to note that Dr. Shadigian, like Dr. Cook, practices medicine in Michigan.

b. THE TRIAL EVIDENCE PROVES THAT CONGRESS ERRED WHEN IT FOUND THAT THERE WAS NO CREDIBLE MEDICAL EVIDENCE THAT PARTIAL-BIRTH ABORTIONS ARE SAFE OR SAFER THAN OTHER ABORTION PROCEDURES AND PARTIAL-BIRTH ABORTION IS NEVER NECESSARY TO PRESERVE THE HEALTH OF WOMEN.

The trial evidence that I have heretofore discussed also disproves Congress' Findings regarding the banned technique's alleged lack of safety and need. I shall not recount it again in detail. However, for the sake of completeness, I will explain why the trial evidence proves that the procedure is needed and safe, and sometimes safer than other procedures. In doing so, I also explain why the contrary Findings of Congress are unreasonable and not supported by substantial evidence.

In order to find that the banned procedure is not safe or not needed, I would have to find that the numerous and extraordinarily accomplished surgeons who gave testimony in this case and who routinely use the banned technique throughout this country, many at major metropolitan hospitals, do not know what they are doing. For example, despite her stellar background and vast experience, I would have to conclude that Dr. Marilynn Frederiksen is a quack.

Dr. Frederiksen is a 1974 graduate of Boston University Medical School. She completed her pediatric residency at the University of Maryland and her obstetrics and gynecology residency at Harvard University. She also completed fellowship programs at Northwestern University in maternal-fetal medicine and clinical pharmacology. As a full-time faculty mem-

ber, Dr. Frederiksen previously managed Northwestern's abortion service which included educating residents in abortion practices. Dr. Frederiksen has been a member of Northwestern's institutional review board for the last 12 years.

According to Dr. Frederiksen, who conducts her procedures in a hospital operating room, the intact D & E is safe and that is why she uniformly tries to deliver the fetus intact when she uses vaginal surgery to perform an abortion. Indeed, for mid-second-trimester abortions, Dr. Frederiksen believes the intact procedure is always safer than other abortion methods including induction. (Pls.' Ex. 123, Test. Dr. Frederiksen 1051-53.)

In order to find that the banned procedure is unsafe or unneeded, one would have to dismiss the views of highly trained and very experienced physicians like Dr. Frederiksen (procedure is safe and necessary) who have detailed knowledge of the surgical methods under discussion. Then, one would have to accept the contrary views of doctors like Sprang (procedure is unsafe and unneeded), Cook (procedure is unsafe and unneeded), and Clark (procedure is unneeded) who have virtually no experience with abortions.

I have previously described the inexperience of Dr. Sprang and Dr. Cook. Dr. Clark is also inexperienced. Dr. Clark has performed less than 20 induction abortions, "at most a dozen" D & E procedures, and he has never performed an intact D & E. (Def.'s Ex. 891, Test. Dr. Clark 2398-99.)

Choosing this nadir of inexperience over the opinions of physicians like Dr. Frederiksen would be plainly

unreasonable. Such a decision would be founded upon insubstantial, rather than substantial, evidence.

The question of what procedure is "safer" or "necessary" is also straightforward, although it requires slightly more explanation. That explanation requires a reiteration of what the Supreme Court said in *Stenberg*.

The Supreme Court made it clear that words like "safety" and "necessity" in this context do not require absolute proof. Accordingly, the Court said that "[m]edical treatments and procedures are often considered appropriate (or inappropriate) in light of estimated comparative health risks (and health benefits) in particular cases." *Stenberg*, 530 U.S. at 937, 120 S. Ct. 2597. This estimation does not require "unanimity of medical opinion." *Id.* "Where a significant body of medical opinion believes a procedure may bring with it greater safety for some patients and explains the medical reasons supporting that view," that is enough to insulate the procedure from legislative prohibition. *Id.*

Here, a "significant body of medical opinion" believes that the banned procedure is "safer" and "necessary" in two circumstances. I next address those two postulates, and the "significant body of medical opinion" upon which they are founded.

The banned procedure, and its various permutations, is "safer" and "necessary" *generally* because well-trained and very experienced doctors believe that (a) the intact procedure reduces the need for placing forceps into the uterus and cervix thus reducing the risk of trauma to the uterus and cervix; (b) the intact procedure reduces the possibility of retaining fetal parts or fluids in the uterus and retention of fetal parts or fluids can cause death or serious illness; (c) removal of the in-

tact fetus reduces the possibility of exposing maternal tissues to sharp bony fragments stemming from the dismemberment of the fetus; (d) the intact procedure is faster than the standard D & E thus reducing the time and expense of the operation, the risk of hemorrhage, and the risk of complications from anesthesia; (e) these safety advantages are particularly evident when the fetus does not require manual conversion in order to complete the intact procedure; and (f) in these general circumstances, the benefits of the procedure to these women are significant.

The "significant body of medical opinion" that has come to these opinions include doctors who have experience practicing at major metropolitan or teaching hospitals, such as: *Dr. Doe*, an internationally certified obstetrician and gynecologist who has practiced at several big-city hospitals in this and other countries, and who has been performing abortions since 1972; *Dr. Vibhakar*, a board-certified obstetrician and gynecologist and assistant professor at the University of Iowa; *Dr. Broekhuizen*, a board-certified obstetrician and gynecologist at the Medical College of Wisconsin; *Dr. Creinin*, a board-certified obstetrician and gynecologist at the University of Pittsburgh; *Dr. Westhoff*, a board-certified obstetrician and gynecologist and a professor at Columbia University who has performed abortions since 1978; *Dr. Hammond*, a board-certified obstetrician and gynecologist and assistant professor at Northwestern University who has performed abortions for 15 years and who supervises Northwestern's two-year fellowship program in family planning and contraceptive research, which includes teaching abortion procedures; *Dr. Paul*, a board-certified obstetrician and gynecologist, editor-in-chief of one of the standard refer-

ences on abortion, and an associate professor at the University of California at San Francisco, where she teaches abortion techniques to residents and health care providers; and *Dr. Chasen*, a board-certified physician in obstetrics and gynecology and fetal and maternal medicine, who is an associate professor at the Weill Medical College of Cornell University, where he directs the High-Risk Obstetric Clinic and teaches surgical abortion methods, including the D & E and D & X procedures.

That "significant body of medical opinion" also includes practicing physicians like *Dr. Carhart*, who headed the surgery department at the Offut Air Force Base Hospital; *Dr. Knorr*, a board-certified obstetrician and gynecologist who has performed as many as 5,000 to 6,000 abortions a year; and *Dr. Fitzhugh*, a board-certified obstetrician and gynecologist and former assistant chief of the obstetrics and gynecology department at the Malcom Grow Medical Center, Andrews Air Force Base.

A "significant body of medical opinion" also believes the banned procedure is "safer" and "necessary" *in special cases*. Just as Dr. Darney warned Congress that the banned procedure was particularly safe and needed in two special cases, numerous physicians in this case gave me similar examples.

Dr. Cain, who is specially certified in biomedical ethics, obstetrics and gynecology, and gynecologic oncology, and who has served as the chairperson of a department of obstetrics and gynecology at a university, stated that in the case "of cancer of the placenta often diagnosed in the second trimester with severe preeclampsia[,]" where "the least amount of instrumentation possible of the uterine wall is desirable[,]" it is

"much safer for the woman to have an intact D & X to remove the molar pregnancy." (Pls.' Ex. 115, Test. Dr. Cain 177.)

Dr. Hammond, at Northwestern, stated that in the later gestational ages of the second trimester and in the case of a complete placenta previa (where the placenta covers the entire cervical opening), labor induction is always contraindicated and the D & E method (in which Dr. Hammond includes the intact version) is the option of choice. (Pls.' Ex. 124, Test. Dr. Hammond 553-54.) In this circumstance, induction would force the fetus through the placenta previa, causing severe maternal hemorrhage, and thus it is absolutely contraindicated. Abdominal surgery is not a good option because, at this stage of gestation, the uterus is an especially vascular organ and cutting through it results in severe bleeding and also makes the uterus more prone to rupture in later pregnancies. (*Id.*)

Other physicians gave specific examples of special cases where the banned procedure is particularly useful. Those physicians included extraordinarily accomplished surgeons like *Dr. Chasen* at Cornell University (*e.g.*, Pls.' Ex. 121, Test. Dr. Chasen 1582-85 (prior uterine scar contraindicates induction and suggests D & E, including the intact version, as the preferred alternative)) and *Dr. Westhoff* at Columbia (*e.g.*, Pls. Ex. 126, Test. Dr. Westhoff 819 (cardiologists refer patients to Dr. Westhoff for D & E, including the intact version, because prolonged labor is considered dangerous to their patients due to the change in dynamics of the blood supply)).

Congress, and Mr. Ashcroft, argue that there are other physicians who come to a different conclusion. Setting to one side the fact that those physicians are

inexperienced with abortion, the fact that other doctors may disagree is not important. Legally, an abortion procedure is "safe," "safer," and "necessary" when a significant body of medical opinion believes it to be so. Congress and Mr. Ashcroft bore the burden of persuasion to establish that there is no significant body of medical opinion supporting the safety and necessity of the banned procedure. They failed in their effort.

In summary, examined from the perspective of the trial record, substantial evidence is lacking to support Congress' Findings that there is "no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures," and that the banned procedure is "never necessary to preserve the health of a woman." On the contrary, the trial record establishes that there is a significant body of medical opinion that contradicts Congress. No reasonable person could come to a contrary decision.

7. IT IS NOT POSSIBLE IN EVERY CASE TO SAFELY KILL THE NONVIABLE FETUS PRIOR TO AN ABORTION WITHOUT SACRIFICING THE HEALTH OF THE WOMAN. IN ANY EVENT, PRIOR TO VIABILITY, THE ISSUE OF FETAL PAIN IS LEGALLY IRRELEVANT.

During the trial there was some debate, although not much, about whether it was safe to kill a nonviable fetus by injection or by cutting the umbilical cord. This debate was prompted by Mr. Ashcroft, apparently to show that the banned procedure could be used providing the fetus was first killed. Related to this issue was Mr. Ashcroft's assertion that fetuses suffer pain, the banned procedure is very painful to the fetus, and Congress had a substantial interest in selecting abortion methods that are less painful to the fetus. As I shall

next briefly discuss, there is not much to either of these related arguments.

First, nearly everyone agrees that it is not always possible to kill the fetus by injection. That is because injections are sometimes both absolutely and relatively contraindicated. (*E.g.*, Tr. 562, Test. Dr. Knorr (not advisable to cause fetal death by injection when the woman has had a prior surgery or pelvic inflammatory disease causing adhesions); Def.'s Ex. 560, Eleanor A. Drey, et al., *Safety of intra-amniotic digoxin administration before late second-trimester abortion by dilation and evacuation.* 182 Am. J. Obstet. & Gynecol. 1063, 1064 (2000) (certain women were not considered appropriate candidates for killing the fetus by injection "because of significant medical illness or cardiovascular disease, current use of cardiac or antihypertensive medications . . ., maternal weight [significantly] above ideal, difficult maternal venous access, or abnormal serum potassium levels . . . ."); Tr. 1757, Test. Dr. Lockwood ("I would certainly not want to do it in a patient with HIV or hepatitis.").) It is also true that it is not always possible to cut the cord to cause fetal death without subjecting the woman to unwarranted risk. (*E.g.*, Tr. 731, Test. Dr. Carhart (if he can, Dr. Carhart will cut the cord, "but I don't go fishing" because "that's when we are starting to induce more risk than benefit.").)[152] So, the argument that the banned procedure may be used when necessary provided the fetus is first killed is simply untrue as a factual matter.

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[152] As later explained, if the cord is cut after the living fetus has been delivered beyond the relevant anatomical landmarks and if that "overt" act kills the fetus, then the ban may apply to the physician's act of cutting the cord even though the skull is not drained until after the fetus is dead.

Second, a "significant body of medical opinion" believes that inducing fetal death by injection is almost always inappropriate to the preservation of the health of women undergoing abortion because it poses tangible risk and provides no benefit to the woman. Indeed, Dr. Bowes, the government's witness, agreed that "there is no medical reason to subject a woman" to the risk of injection to cause fetal death. (Tr. 974-75, Test. Dr. Bowes.) Many other physicians agree. (*E.g.*, Tr. 347-50, Test. Dr. Vibhakar; Pls.' Ex. 121, Test. Dr. Chasen 1636; Pls.' Ex. 126, Test. Dr. Westhoff 877.)

In fact, while the risk of death or complication is very small, it is not insignificant, and informed consent should first be obtained prior to performing the fetal-killing injection. (Tr. 347-50 (Dr. Vibhakar discussing Pls.' Ex. 110 (Uriel Elchalal, et al., *Maternal Mortality following Diagnostic 2nd Trimester Amniocentesis*, 19 Fetal Diagnosis & Therapy 195, 198 (2004) (recounting the death of two women, one 19 weeks pregnant and the other 21 weeks pregnant, after undergoing transabdominal amniocentesis for prenatal diagnosis of genetic disorders; reporting "several [other] cases of serious maternal complications, especially chorioamnionitis and septic shock"); concluding that: "A full explanation prior to patient's consent is of importance, since maternal mortality, although rare, is a real danger even if the proper precautions are taken.")).)

Given the significant medical authority that counsels against causing fetal demise as a prerequisite to abortion, it is no answer to argue that a physician may use the banned procedure but must first kill the nonviable fetus. Any such compulsion would mean that women are subjected to unnecessary, potentially lethal risks for the sake of a fetus that will die anyway.

Third, an issue may be important, but not legally relevant. Prior to viability, that is the case with "pain."[153] Thus, while I assume that a nonviable fetus is capable of suffering "pain" at some point during its gestation, before the fetus becomes viable, the issue of fetal pain is not legally relevant or, if it is legally relevant, it is only marginally so.[154]

Before viability, any abortion—be it a spontaneous abortion (miscarriage), a surgical abortion, or an induction abortion—will (1) result in the death of the fetus and (2) also presumably cause the fetus "pain." In a miscarriage or induction abortion, and also where the fetus is removed by surgery from the woman's belly, the nonviable fetus ("baby" if you prefer) will die because it cannot breathe. In a standard D & E abortion, the nonviable fetus dies because it is torn apart. With an intact D & E abortion, the nonviable fetus will die by a blow to the skull. If the nonviable fetus is killed by an injection to the heart, that beating organ will be pierced by a sharp instrument and stopped as a poison is in-

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[153] "Pain" is important because everyone—especially including every last doctor, lawyer, and judge in this case—opposes the unnecessary infliction of distress on any living organism, no matter its stage of development, and no matter whether one uses "baby," "infant," "fetus" or some other word to describe the life form.

[154] Prior to trial, when deciding a motion in limine, I ruled that the issue of fetal pain appeared to be relevant after viability, but probably only marginally relevant prior to viability. (Filing 105.) After further considering the matter, I conclude the issue of "fetal pain" prior to viability is either totally irrelevant or so marginally relevant as to be meaningless when it comes to deciding the constitutionality of the statute as it applies prior to viability. Since I do not reach the question of whether the statute is constitutional as applied to abortions where the fetus is undisputably viable, I give no further consideration to the question of fetal pain after viability.

jected into it. If the nonviable fetus's cord is cut, the infant will die by asphyxiation.

Since the nonviable fetus will die in any event, and presumably suffer "pain" in every event, the unverifiable views of Congress about which procedure is less or more painful can never trump the clear health interests of the woman when it comes to the selection of abortion methods.[155] If a judge reads *Stenberg* believing that he or she has an obligation to apply it in good faith, it is impossible to argue with a straight face that (1) causing a nonviable fetus to die a gasping, suffocating, and sometimes prolonged, death (induction) inflicts less pain than a single strike to the skull (the banned technique), and (2) therefore the physician's judgment about which procedure is safer for the woman must give way to government officials' aesthetic preferences.[156] Prior to viability, the precedent that I have sworn to follow dictates that the well-founded health interests of the woman are always superior to Congress' otherwise laudable, but ultimately capricious, concern for fetal pain. *Stenberg*, 530 U.S. at 930-31, 120 S. Ct. 2597 (commenting upon Nebraska's desire to prevent "cruelty to partially born children," the Supreme Court em-

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[155] No question is presented in this case about whether it would be legally permissible to require fetal anesthesia in every type of abortion procedure when it might be safe for the woman to do so. I therefore have no occasion to address this separate and distinct question. However, and despite the vilification of Dr. Carhart, it is worth noting that in conjunction with his use of digoxin, the doctor has personally decided to use lidocaine in an attempt to anesthetize the nonviable fetus when he believes it safe for the woman to cause fetal death by injection. (Tr. 629-30.)

[156] As Mr. Ashcroft's witness Dr. Lockwood readily agreed, there is no medical basis "whatsoever" to distinguish between D & E and intact D & E "from the perspective of fetal pain." (Tr. 1763.)

phasized that the government's "interest in regulating abortion previability is considerably weaker than post-viability" and holding that the government cannot enact regulations that "force women to use riskier methods of abortion.").

Fifth, while I am perfectly willing to assume, for the sake of argument, that a nonviable fetus can suffer pain at some point at or after 20 weeks, because nonviable fetal pain is legally irrelevant, it is not necessary, and to be truthful, it is impossible, to decide precisely when, if at all, a nonviable fetus feels pain. The evidence establishes to a virtual certainty that human fetuses lack the anatomy and physiology to perceive pain prior to 20 weeks. After that, the trial evidence convinces me that it is not possible to pinpoint when a fetus develops sufficiently such that it has the physical ability to perceive pain. Following a thorough cross-examination about the different medical opinions on this subject (Tr. 1058-68, Test. Dr. Anand) and the ambiguity of the data, Dr. Anand, the government's credible pain expert who believed a fetus could feel pain at about 20 weeks, admitted that "there is disagreement in the medical community on the issue of whether fetuses, at 20 weeks and later, are able to feel pain." (Tr. 1068, Test. Dr. Anand.)[157] Indeed, the Royal College of Obstetricians and Gynecologists has concluded that fetuses are unable to feel pain the way humans feel pain until 26 weeks. (Ex. 122, Test. Dr. Creinin 722.)

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[157] Based upon a literature review, one law student, after first suggesting that it was probably 20 weeks, has stated that a fetus "almost definitely experiences pain by the twenty-eighth week." Note, *The Science, Law and Politics of Fetal Pain Legislation*, 115 Harv. L. Rev. 2010 (2002).

In the same vein, and because of the lack of legal relevancy, I decline to decide whether a nonviable fetus suffers pain as humans suffer pain. Besides, that decision requires a meaningful understanding of "consciousness" and there is no such understanding. (Tr. 1072-73, Test. Dr. Anand (there is no consensus in the medical community about when fetal consciousness occurs, if at all).)

B. BECAUSE THE BAN REACHES THE D & E ABORTION METHOD USED BY PHYSICIANS LIKE DR. CARHART, THE LAW IS AN UNDUE BURDEN AND UNCONSTITUTIONAL.

The *Stenberg* decision also dealt with an ambiguity in the Nebraska law that threatened to ban procedures other than "partial-birth abortions." In particular, the Court found that the plain language of Nebraska's ban also covered "the most commonly used method for performing previability second trimester abortions[,]" D & E procedures. *Stenberg*, 530 U.S. at 945, 120 S. Ct. 2597. Because "Nebraska [did] not deny that the statute imposes an 'undue burden' *if* it applies to the more commonly used D & E procedure[,]" *id.* at 938, 120 S. Ct. 2597 (emphasis in original), the Court struck down the ban as being an undue burden. *Id.* at 945-46, 120 S. Ct. 2597.

Mr. Ashcroft takes a position similar to that taken by Nebraska. In other words, he does *not* assert that the ban is constitutional even if it applies to D & E abortions. This is probably because, as his counsel frankly admitted, the D & E method has "a fairly remarkable safety record." (Tr. 191.)

Although the safety differences generally even out at or after 20 weeks, D & E abortions are typically safer

than medical-induction abortions during all the gestational ages under consideration in this case. D & E procedures certainly involve less pain and expense than inductions. Furthermore, in many states (like Nebraska) it is not possible to receive an elective induction abortion in a hospital because the hospitals refuse to allow those procedures to be performed. Still further, inductions are contraindicated for some patients. Thus, for millions of women abortion in a hospital using the induction method is simply not an option. In addition, the evidence overwhelmingly demonstrates that a hysterectomy and a hysterotomy, which involve major abdominal surgery, are the most dangerous of all abortion procedures. Many competent physicians consider them the options of "last resort."

In any event, I both find and conclude that, during the second trimester, a law banning D & E abortions would be an undue burden because it would ban the most commonly used method of abortion which is also, generally, the safest method. Such a conclusion is even more true if, as Mr. Ashcroft contends, the ban also extends to D & X or intact D & E abortions. As earlier noted, those abortions are a safe, or sometimes safer, variant of the D & E method.

When addressing the D & E question, and in addition to those principles discussed earlier, the *Stenberg* Court announced the following rules that I must follow in this case:

* Even if a "statute's basic aim is to ban" one procedure, if "its language makes clear that it also covers a much broader category of procedures[,]" the statute will be construed according to its "plain language" and, if that plain language

covers other procedures, the statute must be read to cover all those procedures. *Id.* at 939, 120 S. Ct. 2597.

* While the courts have a " 'duty to give [the law] a construction . . . that would avoid constitutional doubts[,]' " such an interpretation must not " 'twist the words of the law and give them a meaning they cannot reasonably bear.' " *Id.* at 941, 120 S. Ct. 2597 (citation omitted).

* "When a statute includes an explicit definition, we must follow that definition, even if it varies from that term's ordinary meaning." *Id.* at 942, 120 S. Ct. 2597 (citations omitted).

* "'[I]dentical words used in different parts of the same act are intended to have the same meaning[.]' " *Id.* at 944, 120 S. Ct. 2597 (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 570, 115 S. Ct. 1061, 131 L. Ed. 2d 1 (1995)).

The Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531, provides criminal punishment for "[a]ny physician who, in or affecting interstate or foreign commerce, knowingly performs a partial-birth abortion and thereby kills a human fetus[.]" The term "partial-birth abortion" means an abortion in which the person performing the abortion:

(A) deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of

performing an overt act that the person knows will kill the partially delivered living fetus; and

(B) performs the overt act, other than completion of delivery, that kills the partially delivered living fetus . . . .

Id. § 1531(b)(1).

In part, I agree with the plaintiffs' argument that the ban as drafted, and construed according to the principles stated in *Stenberg*, reaches certain D & E abortions. Because D & E abortions are the most common form of abortion in the second trimester, and because they are generally the safest method of abortion during the second trimester, a law like this one which prohibits such a procedure is an undue burden.

However, in part, I also disagree with the plaintiffs. I do not agree that the ban could reasonably be read to pertain to medical inductions or spontaneous abortions and to certain other D & E abortions if I adopt Mr. Ashcroft's proposed "specific intent" limiting construction.

1. THE "SPECIFIC INTENT" LIMITING CONSTRUCTION MAKES THE LAW INAPPLICABLE TO INDUCTION ABORTIONS, TREATMENT OF SPONTANEOUS ABORTIONS, AND CERTAIN D & E ABORTIONS.

The evidence made clear, and Mr. Ashcroft tacitly concedes, that the Act could be interpreted to reach far beyond "partial-birth abortions." Indeed, instead of stating what the Act did not cover (such as D & E abortions, induction abortions, and treatments for spontaneous abortions), Congress was silent on the matter. Physician after physician expressed sincere doubt

about how far the ban extended. Their problem is made more acute because Congress did not endeavor to define either prohibited or permitted conduct by reference to commonly accepted medical terms.

Essentially, many doctors worry that they could start out intending to perform one procedure not banned by the Act, but end up doing another procedure that might appear to be similar to the procedure described in the ban. Thus, and particularly because the statute does not use commonly accepted medical terms, a whole host of physicians understandably worry that they could be subject to prosecution for a federal felony when they had no intention of performing the banned procedure, but the exigencies of the situation forced upon them the necessity of doing something that looked similar to the banned procedure.

In order to overcome these legitimate concerns, Mr. Ashcroft asserts that: "Unless a physician begins a particular abortion with a pre-meditated and specific intent to perform the abortion in the manner the Act forbids, the physician has not acted in violation of the statute, even if it so happens, as he or she proceeds, that the fetus's head gets stuck, and must be crushed, or its contents removed, to complete the delivery." (Filing 161, Def.'s Br. at 87.) "In other words, a physician cannot violate the Act unless he or she forms a specific intent, before delivering the fetus, to perform an overt act in mid-delivery (at the specified anatomic threshold) that will kill the partially delivered fetus." (Filing 161, Def.'s Br. at 86.) As a result, Mr. Ashcroft proposes that I limit the statute using this "specific intent" construction.

As *Stenberg* made clear, I have an obligation to construe the statute to be constitutional so long as I do not

"'twist the words of the law and give them a meaning they cannot reasonably bear.'" *Stenberg*, 530 U.S. at 941, 120 S. Ct. 2597 (citing the Eighth Circuit's decision below, *Stenberg*, 192 F.3d at 1150). The statute challenged here uses a sequential and chronological step-by-step description of the culpable conduct. It describes three discrete and reasonably specific elements, and couples them to reasonably precise states of mind, to wit:

1. The doctor must "deliberately and intentionally" (a) vaginally deliver (b) a living fetus until, (c) in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in a breech presentation, any part of the fetal trunk past the navel is outside the body of the mother.

2. The physician must deliver the living fetus for the specific "purpose" of performing an "overt act" that the provider knows will kill the partially delivered fetus.

3. To complete a "partial-birth abortion," the attending physician must perform "the overt act," other than completion of delivery, that kills the partially delivered living fetus, and he or she must do so "knowingly."

Unlike the Nebraska statute in *Stenberg* which used "substantial portion" and "delivers vaginally" when trying to describe the prohibited procedure, the ban in this case is more specific. It describes the culpable conduct, in sequence, with regard to specific anatomical features of the fetus ("fetal head" or "fetal trunk past the navel") and with regard to a specific anatomical

point with regard to the woman ("outside the body" of the woman). Most importantly, to become liable, the Act requires the physician to "vaginally deliver[] a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the *purpose* of performing an overt act that the person knows will kill the partially delivered living fetus[.]" 18 U.S.C. § 1531(b)(1)(A) (emphasis added).

Given these factors, and particularly because of the "purpose" language, I agree that the statute must be construed to impose upon the government the obligation to prove the *specific intent* urged by Mr. Ashcroft.[158] *See, e.g., United States v. Bailey*, 444 U.S. 394, 404-05, 100 S. Ct. 624, 62 L. Ed. 2d 575 (1980) (construing the federal escape statute and discussing the Model Penal Code's approach; explaining the various meanings of the word "intent"; indicating that the word "intent" can be understood as having a "hierarchy . . . in descending order of culpability, as purpose, knowledge, recklessness, and negligence"; stating that "a person who causes a particular result is said to act purposefully if "'he consciously desires that result, whatever the likelihood of that result happening from his conduct'" and "'purpose' corresponds loosely with the common-law concept of specific intent'") (quoting *United States v. United States Gypsum Co.*, 438 U.S. 422, 445, 98 S. Ct. 2864, 57 L. Ed. 2d 854 (1978) (other citations omitted)).

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[158] Mr. Ashcroft's concession makes proof that the Act has been violated extremely difficult. That, of course, is of no immediate concern to me.

In short, Mr. Ashcroft's "specific intent" construction neither misconstrues nor rewrites the statute when I examine the ban's words, sequential and chronological structure, and evident purpose. Therefore, unless a physician begins a particular abortion with a pre-meditated and specific intent to perform the abortion in the manner the Act forbids, the physician has not acted in violation of the statute, even if it so happens, as he or she proceeds, that the fetus's head gets stuck and must be crushed, or its contents removed, to complete the delivery.

The foregoing construction forecloses application of the statute to medical induction or spontaneous abortion situations. In those situations, the physician never begins his or her treatment with a pre-meditated and specific intent to perform an overt lethal act in mid-delivery when the relevant portion of the fetus (the head or fetal trunk past the navel) has been delivered outside the woman's body. This construction also protects certain doctors who perform D & E abortions, but who always begin that procedure with the sole intent of bringing the fetus out in pieces of undetermined size from the start of the procedure to the end of it, and regardless of the placement of the fetus with respect to the woman's anatomy. Stated differently, physicians who intend only to perform a D & E, as well as physicians performing induction or treating spontaneous abortions lack the specific intent, prior to the beginning of the procedure, to deliver a living fetus past a specific anatomical point on both the fetus and woman, and only then, in mid-delivery, inflicting the killing act.

2. DESPITE THE "SPECIFIC INTENT" LIMITING CONSTRUCTION, THE LAW APPLIES TO CERTAIN [illegible] ABORTIONS.

This construction does not, however, foreclose application of the Act to doctors who have a dual intention at the beginning of the procedure. This is particularly true for the surgical abortions performed by Dr. Carhart during and after 14 weeks but before 18 weeks when he intends to perform the intact procedure or a standard D & E abortion on a living fetus.

Indeed, and apparently seeking to avoid this problem, some of the most ardent physician-supporters of the ban unsuccessfully tried to convince Congress to limit the ban to 20 weeks and after. A defense witness, Dr. Cook, who had twice appeared before Congress in support of the ban, addressed this problem at trial. In response to a question on redirect examination from government's counsel about why Dr. Cook had offered the 20-week cutoff, Dr. Cook responded that he had "offered a gestational age limit to try to bring some greater *narrowness* to the definition." (Tr. 1451 (emphasis added).)

Congress, and Dr. Cook, had good reason to be concerned about the lack of statutory "narrowness" in the 12- to 17-week age range (and thereafter). I discuss that matter next.

At 17 weeks, for example, Dr. Carhart, who does not then induce fetal demise by injection, either (1) extracts the fetus intact after puncturing and draining[159] the skull (about 5% of the time) or (2) extracts the fetus in

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[159] Sometimes Dr. Carhart can manually compress the skull, and thus reduces it. Even so, the compression of the skull is likely to be lethal.

large pieces (about 95% of the time). In other words, Dr. Carhart always has the specific intent to do either a D & E or the banned procedure on a living fetus when he begins the abortion during this age range. But he does not know which procedure he will perform until he has performed it. In both circumstances, the intact fetal body past the navel may be outside the woman's body prior to the time the lethal act (reducing the skull or tearing the body) takes place.

Alternative (1) or (2) above depends upon whether the fetus presents feet-first or in some other configuration. If the fetus presents feet-first, and if the fetal tissue does not tear apart because of its inherent weakness, Carhart will deliver all the fetus save for the skull (which is trapped by the cervix). At that point, he punctures and drains the skull and removes the fetus intact. If the fetus does not present feet-first, or even if it does, and he cannot remove the fetus up to the head, he will bring out as much of the fetal body as he can before he dismembers it.

Carhart's intention at the inception of the procedure is the same; that is, without manually converting the fetus to a footling breech, the doctor, with premeditated and specific intent, desires to extract the fetus in whole or in part using the fewest uterine-cervical passes possible. This always means that the doctor attempts to extract the fewest number of pieces possible and, hopefully, an intact fetus. In other words, if the doctor cannot remove the fetus in one piece, he hopes to remove it in two large pieces, and if that is not possible, in three slightly smaller pieces, and so forth. He always specifically intends to limit the number of passes into the uterus and cervix.

In either circumstance, whether intact or in pieces, the fetus can be "alive" (but clearly not viable) at the time the surgical extraction begins and at the time the killing act is administered. In both circumstances, the hand movements used by Dr. Carhart in pulling the fetal body from the uterus through the cervix into the vagina and then outside the body of the woman are the same. In both circumstances, the amount of dilation used is the same. In both circumstances, either by puncturing and draining only the skull or tearing the fetus into pieces, the living fetus is killed.[160] In both circumstances the fetus is killed in mid-delivery—either by dividing it into two or more pieces, sometimes after

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[160] Dr. Carhart, like many other physicians, does not believe it safe to induce fetal demise by injection at 17 weeks and earlier. Furthermore, and although he sometimes tries to do so before crushing the skull, it is potentially dangerous and sometimes impossible to cut the fetal cord. Even if he cuts the cord, the fetus may still display signs of life before it dies. Supporters of the ban (like Dr. Cook) acknowledge that cutting the cord, or merely allowing the compression of the skull and cervix against the cord to occlude it, will not immediately kill the fetus, and one might have to wait up to 15 minutes before the fetus dies. (Tr. 1464, Test. Dr. Cook.) Waiting, of course, means that the surgery is artificially interrupted with no benefit to the woman. Interruption of the surgery also entails appreciable risk to the woman by extending the time of the operation and, among other things, increasing the possibility of unnecessary blood loss. Still further, if the physician: (1) cuts the cord after delivering the intact fetus beyond the relevant anatomical landmarks and the head of the living fetus lodges in the cervix, (2) waits for the fetus to die as a result of cutting of the cord, (3) reduces the skull to remove the fetus after the fetus has died as a result of cutting the cord, and (4) has the "dual intent," like Dr. Carhart, to perform an intact D & E or a standard D & E, the physician appears to have violated the Act even though the skull is not reduced until after the fetus is dead. (Pls.' Ex. 124, Test. Dr. Hammond 624-25.)

the intact fetal body beyond the navel has been delivered outside the woman, or by reducing the skull and removing the fetus intact, sometimes after the intact fetal body past the navel has been delivered outside the woman.[161]

Dr. Carhart testified that, at 12 through 17 weeks, he "can normally remove" the fetus in "two, three pieces" and "can often get up to the base of the skull, then go back and remove the skull" or "can often get both lower extremities and divide somewhere at the upper part of the spinal cord, removing abdominal organs and some even thoracic organs on the very first removal." (Tr. 627.) Carhart was asked whether, during this gestational age range, he had ever experienced

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[161] Interestingly, in the case of a breech presentation, the law does not preclude a doctor from performing the banned procedure by reducing the skull of an intact fetus unless the fetal body past the navel is outside the woman's body. Although infrequent, the evidence reveals that in some second-trimester abortions the distance from the external portion of the cervix to the vaginal opening may be such that the fetal trunk past the navel cannot physically be drawn outside the woman's body when the head lodges against the cervix. For example, Dr. Doe stated that the distance between the cervix and vaginal opening for his or her D & E abortions is usually 3 inches and can be more. (Tr. 44-45, Test. Dr. Doe.) Dr. Paul stated that the distance could be "four or five inches." (Pls.' Ex. 125, at 65.) Other evidence indicated that between 16 and 18 weeks, a fetus is only 5 to 6 inches long. (Ct.'s Ex. 2.) Thus, it is perfectly possible and perfectly legal to perform the banned procedure where the distance between the cervix and the vaginal opening is too long to permit the intact fetal body past the navel to be delivered outside the woman's body when the head is trapped by the cervix. One wonders whether Congress intended such an anomaly. In any event, and among other things, this shows the drafting problems that confront Congress when it tries to write a statute that takes into account the varied anatomy of women and fetuses.

a situation "where the fetus has been not intact, partially dismembered" but "part of the fetal trunk passed . . . [and] the umbilicus has come outside the body of the mother?" (Tr. 618.) He answered "certainly" and then gave examples of separating the fetus into pieces at the level of the elbow, shoulder, scapula, and chest wall. (Tr. 618.) At another point, Carhart testified that, in this gestational age range, between 25 to 40 times a year he extracts the fetus "up to the shoulders where I have to go in and do something else [separating that portion of the fetal body below the shoulders from that part of the body at the shoulders]." (Tr. 728.)

Thus, the evidence shows that Carhart will sometimes deliver an intact living fetus past the navel outside the woman's body, but, performing a standard D & E, the fetal body is thereafter removed in pieces rather than intact. For example, he is sometimes able to get the entire fetal body up to the chest out of the cervix before performing a destructive act, and, critically, the trunk of the fetus past the navel is outside the woman's body. Then, he performs the dismemberment procedure, the hallmark of all D & E abortions.[162] It is in that

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[162] When the fetal body (or a portion of it) is trapped by the cervix, the trapped object resists being pulled. It is this resistance that causes the fetus to separate into pieces. To be precise, a physician is able to dismember the fetus because of the force caused by his or her instrument pulling on the fetal body and the countertraction exerted against the fetal body by the cervix. The countertraction is caused by the internal cervical os trapping the fetal body and retarding the movement of the fetal body as it is pulled by the doctor's instrument. When the force exerted through the instrument exceeds the tensile strength of the trapped fetal body, the fetus separates. This is the mechanism that causes dismemberment in all D & E abortions. In this sense, a D & E performed

and similar circumstances that the ban applies to D & E procedures.[163]

There is nothing in this law, or the construction proposed by Mr. Ashcroft,[164] that suggests that the physician must have the *exclusive* intent to perform the banned procedures. In many other criminal cases, a "dual intent" (purpose) is enough for a conviction. See, e.g., *Anderson v. United States*, 417 U.S. 211, 226, 94 S. Ct. 2253, 41 L. Ed. 2d 20 (1974) ("A single conspiracy may have several purposes, but if one of them—whether primary or secondary—be the violation of a federal law, the conspiracy is unlawful under federal law."); *United States v. Woodward*, 149 F.3d 46, 71 (1st Cir. 1998) ("A defendant may be prosecuted for deprivation of honest services if he has a dual intent,

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by Carhart between 12 and 17 weeks is no different than any other D & E performed by Carhart and most other physicians.

[163] To be fair, however, I agree with Mr. Ashcroft that the Act, properly read, does not reach those situations where, for example, a doctor removes a piece of the rib from the fetal body while the rest of the fetal body is in the uterus. (Filing 161, Def.'s Br. at 96-98.) Simply because a body part above the navel is removed does not trigger the Act. On the contrary, the relevant question under the statute is whether the intact fetal body past the navel has been delivered outside the woman's body before the destructive act takes place.

[164] Mr. Ashcroft could have proposed a limiting construction that explicitly stated that the Act *never* applies to D & E abortions even when the intact fetus was delivered beyond the relevant anatomical landmarks and even where the physician also had the intent to perform the banned procedure at the beginning of the procedure. I do not fault him for failing to propose such a construction. The plain words and sequential structure of the statute, coupled with Congress' rejection of Dr. Cook's 20-week cut-off, would not have fairly supported such a reading.

i.e., if he is found to have intended both a lawful and an unlawful purpose to some degree.").

In summary, and even accepting the government's "specific intent" construction, it is in this "dual intent" situation where the law reaches standard D & E abortions of the kind performed by doctors like Dr. Carhart. Given his specific intent at the inception of the procedure, if Dr. Carhart separates the living fetus into two or more pieces when the intact fetal body past the navel has been delivered outside the woman's body, he violates the law even though he has not delivered an intact[165] fetus, but, on the contrary, has performed a standard D & E.[166]

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[165] As Dr. Vibhakar noted, nowhere in the operative definition of the banned procedure is there a reference to removing the fetus "intact." (Tr. 351-52.) Still further, Deputy Assistant Attorney General Kim made clear during his deposition that the Department has not decided whether the fetus must be removed "intact" in order for the Act to be violated. (Pls.' Ex. 118, Dep. of Kim 94 & 126.)

[166] This real-life scenario was a problem for Mr. Ashcroft's accomplished lawyer. During my questioning, both in opening statement (Tr. 196-98 & 202) and in closing argument (Tr. 1897-1911), counsel struggled to explain the government's position regarding whether the Act covered Dr. Carhart's practice prior to 18 weeks. At one point, counsel candidly admitted: "The question is whether his intent is one of performing the intact procedure or the procedure banned by the Act, and I'm not, you know, I don't know that that's entirely clear with Dr. Carhart prior to 18 weeks." (Tr. 1900.) I make this point not to pick on Mr. Ashcroft's excellent lawyer, but to illustrate why I believe the situation discussed in the text constitutes a real, rather than an imagined, problem with the Act.

C. IF THE GOVERNMENT'S "SPECIFIC INTENT" CONSTRUCTION OF THE STATUTE IS IMPROPER, THEN THE LAW IS UNCONSTITUTIONAL BECAUSE IT IS TOO VAGUE. OTHERWISE, THE STATUTE IS NOT IMPERMISSIBLY VAGUE.

The plaintiffs contend that the law is unconstitutionally vague because it fails to clearly define the medical procedure to which it applies and because various words used in the statute are vague. If Mr. Ashcroft's proposed "specific intent" limiting construction is improper, I agree that the Act is hopelessly vague regarding the medical procedures to which it applies.

On the other hand, if the limiting construction is proper—and although the ban is unconstitutional because it lacks a health exception and because it reaches D & E abortions of the kind performed by Dr. Carhart and others like him—then the law is not unconstitutionally vague with respect to the definition of the medical procedures to which it applies. Furthermore, I disagree with the plaintiffs' second assertion regarding the vagueness of certain of the words used in the statutes.

A law violates the Constitution's "due process of law" guarantee if it is vague. The Constitution requires that Congress "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly" and "provide explicit standards" for those who enforce the law so that "arbitrary and discriminatory enforcement [may] be prevented." *Grayned v. City of Rockford*, 408 U.S. 104, 108, 92 S. Ct. 2294, 33 L. Ed. 2d 222 (1972). A statute is unconstitutionally vague if someone "'of common intelligence must necessarily guess at its meaning.'" *Coates*

v. City of Cincinnati, 402 U.S. 611, 614, 91 S. Ct. 1686, 29 L. Ed. 2d 214 (1971) (citation omitted). As in this case, a greater degree of specificity is demanded for criminal statutes or laws that impact upon the exercise of constitutionally protected rights. *Village of Hoffman Estates v. The Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99, 102 S. Ct. 1186, 71 L. Ed. 2d 362 (1982).

The foregoing notwithstanding, laws, like life, are almost always uncertain as to their precise meaning. "Condemned to the use of words, we can never expect mathematical certainty from our language." *Grayned*, 408 U.S. at 110, 92 S. Ct. 2294. Therefore, so long as a law "'delineates its reach in words of common understanding,'" *id.* at 112, 92 S. Ct. 2294 (citation omitted), the statute "will not be struck down as vague, even though marginal cases could be put where doubts might arise." *United States Civil Serv. Comm'n v. National Ass'n of Letter Carriers*, 413 U.S. 548, 578-79, 93 S. Ct. 2880, 37 L. Ed. 2d 796 (1973) (internal quotation marks and citation omitted).

1. THE "SPECIFIC INTENT" LIMITING CONSTRUCTION SAVES THE STATUTE FROM VAGUENESS.

Mr. Ashcroft has represented that the statute contains three elements and specific scienter requirements. (Filing 161, Def.'s Br. at 82-83.) In particular, he states that:

> *First*, the provider must "deliberately and intentionally" (a) vaginally deliver (b) a living fetus until, (c) in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in a breech presentation, any part of the fetal trunk past the navel is outside the body of the mother. *Second*,

> the provider must deliver the living fetus for the specific purpose of performing an overt act that the provider knows will kill the partially delivered fetus. *Third*, to constitute a partial-birth abortion, the provider must perform "the overt act," other than completion of delivery, that kills the partially delivered living fetus, and must do so "knowingly" by virtue of the requirement that the provider "knowingly perform [ ]" a partial-birth abortion in order to violate the Act. Act, § 3 (codified at 18 U.S.C. § 1531(b)(1)(A), (B)). The failure to meet any of these deliberate, purposeful, and sequential requirements, including their respective elements of scienter, means that the provider has not performed an abortion proscribed by the Act. Only when the physician deliberately and intentionally performs the procedure in the manner, for the specific purpose, and in the sequence proscribed, does the Act's prohibition apply.

(Filing 161, Def.'s Br. at 82-83 (emphasis added).)

I adopt the foregoing statement of the Attorney General as a proper exposition of the elements of the crime and the state of mind required to commit the crime. In my view, Mr. Ashcroft has fairly and objectively construed the statute in a way which does not improperly twist the words, structure, or evident purpose of the statute. In particular, and as earlier discussed regarding the "specific intent" requirement proposed by Mr. Ashcroft, an abortion provider cannot have liability under the Act for an "accidental" "partial-birth abortion," so long as the provider did not begin

the procedure specifically intending to perform the banned procedure.[167]

If the foregoing is true, and while the ban is unconstitutional for other reasons, the law is not unconstitutionally vague. See, e.g., *Posters 'N' Things, Ltd. v. United States*, 511 U.S. 513, 524 & 526, 114 S. Ct. 1747, 128 L. Ed. 2d 539 (1994) (construing a federal criminal statute that banned the interstate sale of drug paraphernalia to require the government to prove that the "defendant knew that the items at issue are likely to be used with illegal drugs"; holding that, as so construed, the law was not void for vagueness; stating that "the scienter requirement that we have inferred in [the statute] assists in avoiding any vagueness problem") (citing and quoting *Hoffman Estates*, 455 U.S. at 499, 102 S. Ct. 1186 (" '[T]he Court has recognized that a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of the notice . . . that [the] conduct is proscribed.' ")).

2. ALTERNATIVELY, IF THE "SPECIFIC INTENT" LIMITING CONSTRUCTION IS IMPROPER, THE BAN IS VOID FOR VAGUENESS.

The decision to accept Mr. Ashcroft's "specific intent" limiting construction is not free from doubt. Indeed, the Supreme Court in *Stenberg* rejected a similar argument proposed by the Nebraska Attorney Gen-

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[167] As noted earlier, if a living fetus is first delivered beyond the relevant anatomical landmarks before the killing act is administered, Mr. Ashcroft's construction does not protect doctors who perform the standard D & E technique, but who begin the procedure specifically intending to do either the banned procedure or a standard D & E.

eral.[168] The Court in *Stenberg* cautioned that a judge should not rewrite the statute and construct limitations that the words of the statute will not fairly support. 530 U.S. at 940-45, 120 S. Ct. 2597.

Mr. Ashcroft endeavors to save the statute by suggesting that the specific intent necessary to commit the crime must be formulated before the procedure begins, but the statute does not explicitly say so. Also, and in addition to use of the "specific intent" word "purpose," the statute uses the "general intent" word "knows" ("for the *purpose* of performing an overt act that the person *knows* will kill the partially delivered living fetus"). "Knows" has been understood by the Supreme Court to criminalize conduct when the actor appreciates "'that the result is practically certain to follow from his conduct, whatever his desire may be as to that result.'" *United States Gypsum Co.*, 438 U.S. at 445, 98 S. Ct. 2864 (holding that the Sherman Act did not require proof that the actor consciously desired to bring the unlawful act to fruition or to violate the law) (quoting W. LaFave & A. Scott, *Criminal Law* 196 (1972)). Arguably, use of the word "knows" dilutes the specific in-

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[168] There are two major differences in this case, however. First, and most importantly, Congress addressed my major concern and the major concerns of the Eighth Circuit and Supreme Court with regard to definitions; that is, instead of using "substantial portion" like Nebraska, Congress used more precise language. *Compare Stenberg*, 530 U.S. at 940, 120 S. Ct. 2597 (rejecting the Nebraska Attorney General's construction that the "statutory words 'substantial portion' mean 'the child up to the head'"). Second, unlike the Nebraska Attorney General, Mr. Ashcroft does have complete control over all federal prosecutors and his instructions to them must be followed. *Compare id.* at 940-41, 120 S. Ct. 2597 (noting that the Nebraska Attorney General's interpretations of state law do not "bind elected county attorneys. . . .").

tent required by the use of the word "purpose" in the same sentence.

Moreover, Congress did not spell out those procedures which were *not* covered by the law, a fact that the *Stenberg* Court found to be significant. 530 U.S. at 939, 120 S. Ct. 2597 ("The language does not track the medical differences between D & E and D & X—though it would have been a simple matter, for example, to provide an exception for the performance of D & E and other abortion procedures."). In the same vein, Congress elected not to use commonly accepted medical terms to help doctors, who use such terms in their day-to-day practices, distinguish between that which is criminal and that which is lawful. In addition, Congress rejected attempts by physician-supporters of the ban (like Dr. Cook) to limit the ban to 20 weeks of gestation and thereafter. These doctors fervently supported the ban, but thought it wise to address the very "vagueness argument" raised in this litigation.[169]

Thus, there is a strong argument that the statute cannot be limited as Mr. Ashcroft proposes[170] because Congress stubbornly refused to follow the Supreme Court's suggestions for clarity and the recommendation of doctors who otherwise supported the ban. Although I believe that I have been faithful to the precedents, I would not be surprised if I was reversed on this point. If I have erred by accepting Mr. Ashcroft's construc-

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[169] Although he thought the vagueness argument "disingenuous," Dr. Cook told me that he proposed the 20-week limitation to "alleviate a large number of discussions and battles over the vagueness argument. . . ." (Tr. 1466, Test. Dr. Cook.)

[170] Indeed, and in a persuasive and well-reasoned opinion, Judge Hamilton so found. *Planned Parenthood Fed. of Am.*, 320 F. Supp. 2d at 977-78.

tion, and that is a close question, then the statute is obviously far too vague. The record demonstrates numerous circumstances where a doctor begins an abortion intending to do a particular procedure, such as a standard D & E, and ends up doing a procedure that is factually identical to the crime created by the ban. In such a circumstance, and in the midst of a surgical procedure, a doctor would, in utter good faith, ask: Does the Act apply to me?[171] Absent the "specific intent" limiting construction, no one, save a jury exercising unguided discretion, could ever know the answer to that question. Doctors would be left in the dark, patients put at real risk, and overly zealous prosecutors emboldened to take improper advantage. In that circumstance, the Act is plainly void for vagueness.

3. ON THIS RECORD, WORDS LIKE "LIVING," "OVERT ACT," "PAST THE NAVEL," "DELIBERATELY AND INTENTIONALLY," AND "IN OR AFFECTING INTERSTATE COMMERCE" ARE NOT IMPERMISSIBLY VAGUE.

In addition to their arguably valid concern that the law is unconstitutionally vague because it fails to define clearly the banned medical procedure, and almost in passing, the plaintiffs also raise concerns about specific words or phrases used in the statute. They mention "living," "overt act," "past the navel," "deliberately and intentionally," and "in or affecting interstate commerce." Plaintiffs spend very little time explaining to me why these terms, when read in context, are truly

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[171] Without Mr. Ashcroft's "specific intent" limitation, Dr. Charles Lockwood, a highly credible government witness, believes the law is "imprecise" and "vague" from the viewpoint of a practicing physician. (Tr. 1739-40.)

vague. Accordingly, I shall respond to their arguments with similar brevity.

While I might be able to conceive of situations where these terms (and others) are vague,[172] it is not my proper role to conjure up marginal cases demonstrating vagueness. Moreover, the evidence reveals that most of the time, doctors have a practical understanding of commonplace words like "living" and "past the navel." In addition, the plaintiffs have failed to cite any cases from the Eighth Circuit Court of Appeals or the Supreme Court holding that standard statutory terms of art (such as "overt act," "deliberately and intentionally," and "in or affecting interstate commerce") are constitutionally vague. Still further, and most importantly, given my adoption of the "specific intent" limiting construction, the reach of the statute, particularly as it regards "accidental" violations, has been substantially narrowed, and the plaintiffs' plainly legitimate vagueness concerns are thereby obviated.

Therefore, until a case comes along that provides a much more developed record and far more detailed briefing for use in deciding whether certain specific words or phrases used in this statute are constitutionally infirm, I decline to declare them to be so.

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[172] The word "living" comes to mind. For example, is a late second-trimester fetus that has a heartbeat, but which has developed without the cranial vault and absent (or possessing only rudimentary) cerebral and cerebellar hemispheres, brainstem and basal ganglia ("anencephaly"), "living"?

D. THE BAN'S "LIFE" EXCEPTION MUST BE CONSTRUED TO MEAN THAT A DOCTOR MAY PERFORM A "PARTIAL-BIRTH ABORTION" IF "NECESSARY" IN HIS OR HER OWN PROFESSIONAL JUDGMENT TO SAVE THE LIFE OF THE WOMAN, AND WHEN SO CONSTRUED THE LAW'S "LIFE" EXCEPTION IS CONSTITUTIONAL.

The Act does not ban a partial-birth abortion that "is necessary to save the life of a mother whose life is endangered by a physical disorder, physical illness, or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself." 18 U.S.C. § 1531(a). The plaintiffs argue that this "life" exception is too narrow because it only applies when it "is necessary to save the life of a mother," 18 U.S.C. § 1531(a), but not when the physician, *in his or her appropriate medical judgment*, believes a partial-birth abortion is necessary to save the life of the woman. They argue that the absence of the "appropriate medical judgment" phrasing within the life exception allows others to substitute their medical judgment for that of the abortionist in determining whether a woman's medical condition was life-threatening and it also makes the law vague.

Under long-standing Supreme Court precedent, whether an abortion is "necessary" to preserve the woman's life or health is determined in the context of the treating physician's professional judgment under the circumstances presented to him or her while caring for the patient. *United States v. Vuitch*, 402 U.S. 62, 69-72, 91 S. Ct. 1294, 28 L. Ed. 2d 601 (1971); *Doe v. Bolton*, 410 U.S. 179, 191-192, 93 S. Ct. 739, 35 L. Ed. 2d 201 (1973). Construed in this manner, the statutory phrase "necessary for the preservation of the mother's life or

health" is not unconstitutionally vague. *Vuitch*, 402 U.S. at 72, 91 S. Ct. 1294; *Bolton*, 410 U.S. at 191-92, 93 S. Ct. 739.

Citing *Vuitch*, the Court in *Roe v. Wade*, 410 U.S. at 165, 93 S. Ct. 705, held that after viability, a state in promoting its interest in human life may choose to regulate and proscribe abortion "except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." This interpretation of the life exception was re-affirmed in *Casey*, 505 U.S. at 879, 112 S. Ct. 2791, and expressly extended to previability abortion procedures in *Stenberg*, 530 U.S. at 937, 120 S. Ct. 2597.

As explained in *Stenberg*, the word "necessary" as used in the phrase "necessary, in appropriate medical judgment, for the preservation of the life or health of the mother" does not refer to an absolute necessity or to absolute proof. Rather, it embodies "the judicial need to tolerate responsible differences of medical opinion" which may arise when doctors' opinions differ concerning the comparative health risks and appropriate treatment options for women seeking or needing an abortion. *Stenberg*, 530 U.S. at 937, 120 S. Ct. 2597.

Whether explaining the constitutional parameters of the right to an abortion or interpreting statutory language regulating that right, the Supreme Court has consistently incorporated the treating physician's professional medical judgment into the meaning of "necessary" for the woman's life and health. When judicial interpretations have settled the meaning of a statutory provision, repeating the same language in a new statute indicates Congress' intent to incorporate the Court's interpretation of that language. *Bragdon v. Abbott*, 524 U.S. 624, 645, 118 S. Ct. 2196, 141 L. Ed. 2d 540 (1998)

(citing *Lorillard v. Pons*, 434 U.S. 575, 580-81, 98 S. Ct. 866, 55 L. Ed. 2d 40 (1978)). That is the case here.

In recognition of the Supreme Court's abortion jurisprudence and established principles of statutory construction, Mr. Ashcroft concedes, as he must, that although the Act does not expressly say it, the life exception should be interpreted to permit a physician to perform a partial-birth abortion if it is "necessary" in his or her own professional judgment to save the life of the mother. (Tr. 1911-13; Filing 161, Def.'s Br. at 98.) Likewise, I conclude that the Act's exception allowing partial-birth abortions when it "is necessary to save the life of a mother," 18 U.S.C. § 1531(a), means a physician is permitted to perform a partial-birth abortion when the physician, in his or her own professional judgment, believes a partial-birth abortion is necessary to save the woman's life. Construed as such, the life exception is neither unduly narrow in scope nor unconstitutionally vague.

E. WHETHER DESCRIBED AS "FACIAL" OR WHETHER DESCRIBED AS "APPLIED," THE INVALIDATION OF THIS ABORTION-REGULATING STATUTE DOES NOT EXTEND TO SITUATIONS WHERE THE FETUS IS INDISPUTABLY VIABLE. THE RULING SHOULD ALSO BE LIMITED IN SCOPE SO AS NOT TO UNNECESSARILY INTERFERE WITH THE DECISIONS OF OTHER COURTS.

There are two matters that require clarification. The first deals with the reach of my decision. The second deals with the need to avoid potentially conflicting orders in the two other cases that have concurrently been litigated in California and New York.

1. THIS DECISION DOES NOT INVALIDATE THE BAN WHERE THE FETUS IS INDISPUTABLY VIABLE.

Ostensibly, the plaintiffs bring their challenge to the ban as a "facial" rather than as an "applied" objection. (Tr. 163, Opening Stmt. of Pls.' Atty's. ("This is a facial challenge to the Act.").) As I will explain, while the plaintiffs' able lawyers may understand what these words mean in the abortion context, I do not. Moreover, I do not understand the implications of labeling this case a "facial" challenge as opposed to labeling it an "applied" challenge.

Nevertheless, and no matter how it might be labeled by others, I should be clear about what I intend my decision to mean. Therefore, I next proceed to explain what I intend. In doing so, I also explain what I do not intend.

In *Stenberg*, I addressed the "facial" and "applied" distinction. I wrote the following:

> A law may be challenged as unconstitutional in two ways. The law may be challenged "as applied" and "facially." See, e.g., *Ada v. Guam Soc. of Obstetricians & Gynecologists*, 506 U.S. 1011, 1012-13, 113 S. Ct. 633, 121 L. Ed. 2d 564 (1992) (Scalia, J. dissenting); *WMPC II*, 130 F.3d at 193-94; Michael C. Dorf, *Facial Challenges to State and Federal Statutes*, 46 Stan. L. Rev. 235 (1994). If the law is judged unconstitutional on facts peculiar to the plaintiff, then the law is unconstitutional "as applied." *Ada*, 506 U.S. at 1013, 113 S. Ct. 633 (Scalia, J. dissenting). If, on the other hand, the law is found unconstitutional regardless of how it might be applied to a particular plaintiff then the law is said to

> be facially unconstitutional. *Id.* The difference between the two challenges is this: if a law is facially invalid it cannot be enforced against anyone, but if a law is unconstitutional "as applied," while it cannot be enforced against the plaintiff (or others like him), the law is otherwise generally enforceable. *Id.*

Carhart v. Stenberg, 11 F. Supp. 2d 1099, 1119 (D. Neb. 1998). So far as I am able to determine, the foregoing remains a correct, although tautological, statement of the law.

In *Stenberg*, I decided that the Nebraska law was unconstitutional for three reasons: (1) it lacked a health exception; (2) it banned all D & E abortions; and (3) it was too vague. *Id.* at 1132. However, I also found that, although the attack in that case was made both "facially" and as "applied," I should declare the Nebraska statute unconstitutional only as applied to Dr. Carhart and physicians like him. *Id.* at 1120.

I explicitly limited my decision as "applied" to Dr. Carhart (and others like him) in *Stenberg*, and I did so primarily for prudential reasons; that is, I thought it unwise to speculate "about a wide variety of fact patterns that might occur in various unknown surgical suites involving various unknown doctors and patients with various unknown motives and conditions." *Id.* In particular, I refused to make my decision applicable to postviability abortions since Dr. Carhart did not perform those procedures. *Id.* at 1120 & 1132.

On appeal, the Eighth Circuit decided that the ban failed because it extended to D & E abortions, but the Eighth Circuit did not reach the "health exception" or vagueness questions. *Carhart v. Stenberg*, 192 F.3d 1142, 1146 n.4 (8th Cir. 1999) ("Because we are holding

the law unconstitutional on undue-burden grounds, it is not necessary for us to discuss the vagueness issue. Nor is it necessary for us to discuss whether the law creates an undue burden by prohibiting the D & X procedure. The basis for our holding is the undue burden created by the ban of the D & E procedure.").

In so deciding, the Eighth Circuit considered the appeal as if it were "a challenge to the facial validity of an abortion regulation." *Id.* at 1149. In the Eighth Circuit's decision, the test for facial invalidity was stated this way: "If the regulation operates 'as a substantial obstacle to a woman's choice to undergo an abortion "in a large fraction of the cases in which [it] is relevant, . . . [i]t is an undue burden, and therefore invalid."'" *Stenberg*, 192 F.3d at 1149 (quoting *Planned Parenthood, Sioux Falls Clinic v. Miller*, 63 F.3d 1452, 1458 (8th Cir. 1995), in turn quoting *Casey*, 505 U.S. at 895, 112 S. Ct. 2791).

Ultimately, but without clearly stating whether the Court believed the case involved a "facial" or an "applied" challenge, the Supreme Court affirmed the decision of the Eighth Circuit. The Supreme Court decided that the Nebraska statute was unconstitutional because it lacked a health exception, *Stenberg*, 530 U.S. at 930-38, 120 S. Ct. 2597, (a decision I also reached, but the Eighth Circuit refused to reach) and because it also extended to D & E abortions (a decision that both the Eighth Circuit and I reached). *Id.* at 938-46, 120 S. Ct. 2597. Like the Eighth Circuit (but unlike my decision), the Supreme Court did not deal with the vagueness question.

Although the Supreme Court's opinion in *Stenberg* was not clear on the "facial" versus "applied" question, the Supreme Court has very recently suggested that at

least the second part of the *Stenberg* decision—because the ban applied to D & E abortions it was unconstitutional—involved a "facial" invalidation. See *Sabri v. United States*, ___ U.S. ___, ___ - ___, 124 S. Ct. 1941, 1948-49, 158 L. Ed. 2d 891 (2004) (federal statute prohibiting bribery involving federal funds was not facially unconstitutional on grounds that it did not require a nexus between criminal activity and federal funds; stating "that facial challenges are best when infrequent" because such challenges frequently involve" 'premature interpretatio[n] of statutes' on the basis of factually bare-bones records") (quoting *United States v. Raines*, 362 U.S. 17, 22, 80 S. Ct. 519, 4 L. Ed. 2d 524 (1960)).

As pertinent here, the *Sabri* Court said:

> Facial challenges of this sort are especially to be discouraged. Not only do they invite judgments on fact-poor records, but they entail a further departure from the norms of adjudication in federal courts: overbreadth challenges call for relaxing familiar requirements of standing, to allow a determination that the law would be unconstitutionally applied to different parties and different circumstances from those at hand. See, e.g., *Chicago v. Morales*, 527 U.S. 41, 55-56, n.22, 119 S. Ct. 1849, 144 L. Ed. 2d 67 (1999) (plurality opinion). Accordingly, we have recognized the validity of facial attacks alleging overbreadth (though not necessarily using that term) in relatively few settings, and, generally, on the strength of specific reasons weighty enough to overcome our well-founded reticence. See, e.g., *Broadrick v. Oklahoma*, 413 U.S. 601, 93 S. Ct. 2908, 37 L. Ed. 2d 830, (1973) (free speech); *Aptheker v. Secretary of State*, 378 U.S. 500, 84 S. Ct. 1659, 12 L.

> Ed. 2d 992 (1964) (right to travel); *Stenberg v. Carhart*, 530 U.S. 914, 938-946, 120 S. Ct. 2597, 147 L. Ed. 2d 743 (2000) (abortion); *City of Boerne v. Flores*, 521 U.S. 507, 532-535, 117 S. Ct. 2157, 138 L. Ed. 2d 624 (1997) (legislation under § 5 of the Fourteenth Amendment). *See generally* Fallon, *As-Applied and Facial Challenges and Third-Party Standing*, 113 Harv. L. Rev. 1321, 1351 (2000) (emphasizing role of various doctrinal tests in determining viability of facial attack); Monaghan, *Overbreadth*, 1981 S. Ct. Rev. 1, 24 (observing that overbreadth is a function of substantive First Amendment law). Outside these limited settings, and absent a good reason, we do not extend an invitation to bring overbreadth claims.

Sabri, ___ U.S. at ___ - ___, 124 S. Ct. at 1948-49.

From *Sabri* it appears that the Court believes that at least a portion of its invalidation of Nebraska's ban against partial-birth abortion was "facial" in nature. The pinpoint citation in *Sabri* to the *Stenberg* opinion, that is, the citation to 530 U.S. at 938-946, 120 S. Ct. 2597, refers to the question of whether the Nebraska statute also banned D & E abortions. *Sabri*, ___ U.S. at ___, 124 S. Ct. at 1948 ("Accordingly, we have reco g-nized the validity of facial attacks alleging overbreadth (though not necessarily using that term) in relatively few settings, and, generally, on the strength of specific reasons weighty enough to overcome our well-founded reticence. See, e.g., . . . *Stenberg v. Carhart*, 530 U.S. 914, 938-946, 120 S. Ct. 2597, 147 L. Ed. 2d 743 (2000) (abortion). . . .").

With this background in mind, a host of questions arise. Among them are the following:

* Can an abortion statute be declared "facially" unconstitutional for one reason, and unconstitutional only as "applied" for another reason? If so, when is that proper? If so, how does one tailor the relief in each such circumstance and for the case in its entirety?

* Does *Sabri's* citation to a specific portion of *Stenberg* that dealt with the Nebraska ban's coverage of all D & E abortions mean that similar decisions must be treated as "facial" invalidations despite the fact that a trial court might find, as I have found here, that the law covers certain D & E procedures but not others? If so, how does the "large-fraction" test fit?

* Because the *Sabri* opinion did not refer to the "health exception" portion of the *Stenberg* opinion, did the Court mean to imply that such challenges are not properly viewed as "facial" in nature under any circumstance? Indeed, why would the "large-fraction" test for facial invalidity articulated by the Eighth Circuit in *Stenberg* and the Supreme Court in *Casey* ever be appropriate where a law threatens the health of a single woman whether she be among a "large fraction" of women or not?[173] If an abortion regulation is invalid as to one woman because of the lack of a health exception, has the law been declared "facially" invalid as to all women?

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[173] *See, e.g., Stenberg*, 530 U.S. at 934, 120 S. Ct. 2597 ("[T]he State cannot prohibit a person from obtaining treatment simply by pointing out that most people do not need it.").

* Since the Court did not address the vagueness question at all either in *Stenberg* or *Sabri*, how do I treat a finding of vagueness? In particular, and as is the case here, is a finding of vagueness that flows from a finding that the statute is vague only if the limiting construction proposed by the government is improper a "facial" or an "applied" invalidation?

I simply do not know the answers to these questions. Without answers to these questions, and to avoid confusion, I refuse to place a label on my decision using the words "facial" or "applied."

Most importantly, none of the cases that I have examined or that the parties have brought to my attention deal with the most critical question in this area. Regarding the "facial" and "applied" dichotomy, how does a trial court properly apply the substantive law of abortion regulation, depending, as that law does, upon whether the fetus is viable, when the evidence presented to the trial court concentrates almost exclusively upon situations where the fetus is not viable?

It is important to remember that the *Stenberg* Court did not decide or address whether my refusal to invalidate the Nebraska law as it applied to postviability abortions was correct or incorrect. The Eighth Circuit did not address that issue either. Thus, while I must follow these appellate opinions, I have no guidance from my judicial superiors in the *Stenberg* case about how to deal with a suit attacking a statute banning a certain abortion procedure when the evidence before the trial court is directed only at previability abortions, but the remedy sought is invalidation of the law as it also pertains to postviability abortions.

At the beginning of the trial, counsel for the plaintiffs admitted, and the evidence later confirmed, that "all the plaintiffs and all the witnesses are going to be testifying about previability procedures." (Tr. 164, Opening Stmt. of Pls.' Atty's.) At the end of the trial, when I asked how I could apply that previability evidence to the postviability situation, counsel told me that I could "extrapolate." (Tr. 1842, Closing Arg. of Pls.' Atty's.)

As I have earlier indicated when discussing the *Turner* standard of review, since the *Stenberg* Court made clear that physicians do not have "unfettered" discretion in selecting abortion procedures, that must mean that the absence of a health exception for "unnecessary" procedures does not constitute a per se violation of the Constitution. It must also mean that Congress has the right to regulate specific abortion methods. And, although widely criticized, the viability dividing line in the Supreme Court's abortion jurisprudence remains crucial to a good-faith application of the precedents of the Court. As the Supreme Court has made clear, the government's interest in the potentiality of human life is so strong that after viability it may, with certain important qualifications, ban abortion altogether. *Stenberg*, 530 U.S. at 921, 120 S. Ct. 2597 (following "'"viability, the [government] in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."'" (quoting *Casey*, 505 U.S. at 879, 112 S. Ct. 2791, in turn quoting *Roe v. Wade*, 410 U.S. at 164-65, 93 S. Ct. 705)).

If Congress has the abstract power to regulate the "unfettered" discretion of physicians regarding abortion methods, and the viability dividing line is so important that Congress has the abstract power to ban abortions entirely after viability, then surely I ought to insist upon concrete evidence tailored to that time frame before I invalidate an Act of Congress that regulates abortion during that time frame. If that is so, then this case presents an insurmountable obstacle to declaring the law unconstitutional when applied to a fetus that is undisputably viable.

While I have had no doctor testify before me regarding situations where the fetus is undisputably viable, I know from the congressional record that Dr. Warren Hern does postviability abortions using the banned technique, but he kills the fetus prior to beginning the procedure. I know also from the congressional record that postviability abortions, apparently using the banned technique, are conducted in Kansas, but I know very little more than that.

Should I speculate that a health exception is unnecessary in the postviability situation because Dr. Hern is, apparently, always able to destroy the fetus prior to commencing a postviability procedure? On the other hand, can I reasonably conclude that a health exception is really necessary in the postviability situation because in the previability age range that is so? On this record, and as opposed to the previability period, the answers to these questions would be highly speculative.

If the Supreme Court's precedents are to be rigorously applied by me, judicial validation of a surgery as medically necessary, which would effectively authorize the crushing of the skull of an *indisputably viable* fetus in the name of a woman's health, particularly in the face

of a congressional prohibition, requires more than the "extrapolation" proposed by the plaintiffs. It, at least, requires the explanatory testimony of physicians who would perform such procedures. Absent that evidence, I can only guess. I refuse to do so.

Therefore, I will declare the law unconstitutional in all of its applications when the fetus is not viable or when there is a doubt about the viability of the fetus in appropriate medical judgment of the doctor performing the abortion. To be precise, unless the fetus is indisputably viable, my decision protects the physician when he or she performs a partial-birth abortion in the exercise of appropriate medical judgment.[174]

I do not determine whether or not the law is constitutional when the fetus is indisputably viable. In this court, that legal issue remains an open question. However, the government would be well-advised to seek an answer to that question before it commences a criminal prosecution. Only an over-zealous prosecutor would seek an indictment against a physician who performed a partial-birth abortion on a viable fetus without first

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[174] The time when "viability" is generally thought to occur has decreased as medicine has developed new and better ways of treating premature infants. Even so, the definition of when "viability" is generally thought to occur changes from institution to institution, fetus to fetus, and physician to physician. In addition to the evolving standard of when viability generally occurs, viability in a given instance turns on a wide range of factors. Thus, in the inevitable cases where there is uncertainty about viability, the abortionist's appropriate medical judgment must prevail. Using this standard, physicians will not fear using the banned procedure in situations where viability is questionable. Even if they are wrong about viability, the government is prohibited from enforcing this law against those doctors unless the fetus was indisputably viable.

seeking some type of judicial declaration that the statute is enforceable in that circumstance.

And, finally, whether I have declared the law "facially" unconstitutional or as "applied," I do not know. I leave that for others to determine.

2. MY DECISION MUST BE TAILORED TO AVOID CONFLICTS WITH OTHER COURTS.

Other cases similar to this one are in the process of being litigated in New York and California and perhaps elsewhere. This, obviously, raises the specter of conflicting injunctions and declarations.

Injunctions should never be broader than necessary to afford complete relief to the plaintiffs. *Califano v. Yamasaki*, 442 U.S. 682, 702, 99 S. Ct. 2545, 61 L. Ed. 2d 176 (1979) ("[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs."). This is particularly true in cases of nationwide importance because a broad injunction may interfere with or preclude other courts from ruling on the constitutionality of such matters. *Virginia Soc. for Human Life, Inc. v. FEC*, 263 F.3d 379, 393 (4th Cir. 2001) (a regulation that violated the First Amendment rights of an issue advocacy group did not justify the district court's injunction against enforcement of the regulation against other parties elsewhere in the United States). Such interference is contrary to the limited jurisdiction of a federal district court. Still further, an expansive injunction may "deprive the Supreme Court of the benefit of decisions from several courts of appeals." *Id.*

These same concerns are present when the court declares a statute to be unconstitutional. In a case like this one, this court has no power to speak for any other

federal court, and no other federal court is bound to follow this decision.

Therefore, I will do as I did when I issued the temporary restraining order in this case. See *Carhart v. Ashcroft*, 287 F. Supp. 2d 1015, 1016 (D. Neb. 2003). Essentially, I will limit the protection of the injunction to the plaintiffs and those with whom they deal in the course of their medical practice In addition, as noted above, the declaration of unconstitutionality and the resulting injunction will be limited to those situations when the fetus is not viable or when there is a doubt about the viability of the fetus in the appropriate medical judgment of the doctor performing the abortion. Finally, in no sense do I intend my ruling to be binding upon other courts.

III. CONCLUSION

Before summarizing my opinion, a word about the lawyers is in order. The lawyers for both sides were magnificent. They are smart, fair-minded, candid, civil, professional, ethical, good writers, excellent speakers, and accomplished trial lawyers. They represent the very best the legal profession has to offer, and I sincerely thank them for their work in this case.

I have decided that the Partial-Birth Abortion Ban Act of 2003 is unconstitutional. In particular, I have decided that the law is unconstitutional because: (1) it lacks a health exception; (2) accepting Mr. Ashcroft's proposed "specific intent" limiting construction, the law nevertheless bans D & E abortions of the type performed by Dr. Carhart when he does not first induce fetal death by injection prior to 18 weeks; and (3) if Mr. Ashcroft's proposed "specific intent" limiting construc-

tion is improper, the law is too vague regarding the behavior the law seeks to criminalize.

On the other hand, I do not agree that the law, properly limited, bans certain D & E abortions where the physician lacks the requisite specific intent. Similarly, when a physician conducts induction abortions or when a physician treats spontaneous abortions, he or she lacks the requisite specific intent and therefore the law does not ban those activities. Moreover, I do not believe the law is too vague because of the use of certain words. In addition, I do not agree that the ban's "life" exception is unconstitutional when it is properly construed. In addition, my ruling does not apply where the fetus is indisputably viable. Finally, I decline to issue a "nationwide" injunction.

Accordingly,

IT IS ORDERED that:

1. Judgment shall be entered by separate document for the plaintiffs and against the defendant substantially as provided in paragraphs 2 through 4 below.

2. The Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531, is declared to be unconstitutional in all of its applications when the fetus is not viable or when there is a doubt about the viability of the fetus in the appropriate medical judgment of the doctor performing the abortion. The court does not determine whether the Partial-Birth Abortion Ban Act of 2003 is constitutional or unconstitutional when the fetus is indisputably viable.

3. In all cases when the fetus is not viable or when there is a doubt about the viability of the fetus in the appropriate medical judgment of the doctor performing the abortion, John Ashcroft, in his official capacity as Attorney General of the United States, and his employees, agents, and successors in office, are permanently enjoined from enforcing the Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531, against the plaintiffs and their officers, agents, servants, and employees, including those individuals and entities (both medical and non-medical) with whom the plaintiffs work, teach, supervise, or refer.

4. Costs are taxed to the defendant.

5. Within 20 days, Plaintiffs shall post a bond in the sum of $500.00 pursuant to Fed. R. Civ. P. 65(c) and 65.1.

6. Any application for attorney fees shall be submitted no later than 20 days following the entry of judgment. If such an application is filed, the defendant shall have 20 days thereafter to respond.

Exhibit Number	Bluebook Citation	Westlaw Citation
Ct's Ex. 4	Partial-Birth Abortion: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong. (1995).	Document not available in complete form on Westlaw.
Ct's Ex. 5	The Partial-Birth Abortion Ban Act of 1995: Hearing on H.R. 1833 Before the Senate Comm. on the Judiciary, 104th Cong. (1995).	Document not available in complete form on Westlaw.
Ct's Ex. 6	Effects of Anesthesia During a Partial-Birth Abortion: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong. (1996)	Document not available in complete form on Westlaw.
Ct.'s Ex. 7	Partial-Birth Abortion; The Truth: Joint Hearing on S. 6 and H.R. 929 Before the Senate Comm. on the Judiciary and the House Comm. on the Judiciary, 105th Cong. (1997).	Document not available in complete form on Westlaw.
Ct.'s Ex. 8	Partial-Birth Abortion Ban Act of 2002: Hearing on H.R. 4965 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 107th Cong. (2002).	Document not available in complete form on Westlaw.
Ct.'s Ex. 9	Partial-Birth Abortion Ban Act of 2003: Hearing on H.R. 760 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 108th Cong. (2003).	Document not available in complete form on Westlaw.
Ct.'s Ex. 10	H.R. Rep. No. 108-58 (2003).	2003 WL 1789189 (Leg. Hist.)
Def.'s Ex. 502	H.R. Rep. No. 108-58, at 1 (2003).	2003 WL 1789189 (Leg. Hist.)
Def.'s Ex. 503	Partial-Birth Abortion Ban of 2003: Hearing on H.R. 760 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 108th Cong. 1 (2003).	Exhibit is title page; not available on Westlaw.
Def.'s Ex. 504	Partial-Birth Abortion Ban Act of 2002: Hearing on H.R. 4965 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 107th Cong. 1 (2002).	Exhibit is title page; not available on Westlaw.
Def.'s Ex. 505	Partial-Birth Abortion; The Truth: Joint Hearing on S. 6 and H.R. 929 Before the Senate Comm. on the Judiciary and the House Comm. on the Judiciary, 105th Cong. 1 (1997).	Exhibit is title page; not available on Westlaw.
Def's Ex. 506	Effects of Anesthesia During a Partial-Birth Abortion: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong. 1 (1997).	Exhibit is title page; not available on Westlaw.
Def.'s Ex. 507	The Partial-Birth Abortion Ban Act of 1995: Hearing on H.R. 1833 Before the Senate Comm. on the Judiciary, 104th Cong. 1 (1995).	Exhibit is title page; not available on Westlaw.

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Def.'s Ex. 508	Partial-Birth Abortion: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong. 1 (1995)	Exhibit is title page; not available on Westlaw.
Def.'s Ex. 509	148 Cong. Rec. E1,0967-97 (daily ed. June 19, 2002).	2002 WL 1337996 (Cong. Rec.)
Def.'s Ex. 510	148 Cong. Rec. H5,352-374 (daily ed. July 24, 2002).	2002 WL 1676699 (Cong. Rec.)
Def.'s Ex. 511	148 Cong. Rec. H5,353-54 (daily ed. July 24, 2002).	2002 WL 1676699 (Cong. Rec.)
Def.'s Ex. 512	148 Cong. Rec. H5,346-352 (daily ed. July 24, 2002).	2002 WL 1676684 Cong. Rec.)
Def.'s Ex. 513	148 Cong. Rec. 5,346 (daily ed. July 24, 2002).	2002 WL 1676684 (Cong. Rec.)
Def.'s Ex. 514	149 Cong. Rec. E249-250 (daily ed. Feb. 13, 2003).	2003 WL 330476 Cong. Rec.)
Def.'s Ex. 515	149 Cong. Rec. S2,522-23 (daily ed. Feb. 14, 2003).	2003 WL 330308 (Cong. Rec.)
Def.'s Ex. 516	149 Cong. Rec. S3,383-399 (daily ed. Mar. 10, 2003).	2003 WL 939675 (Cong. Rec.) 2003 WL 939679 (Cong. Rec.)
Def.'s Ex. 517	149 Cong. Rec. S3,422-29, S3456-494 (daily ed. Mar. 11, 2003).	2003 WL 1025142 (Cong. Rec.) 2003 WL1025150 (Cong. Rec.)
Def.'s Ex. 518	149 Cong. Rec. S3,560-3,614 (daily ed. Mar. 12, 2003).	2003 WL 1088102 (Cong. Rec.) 2003 WL 1088103 (Cong. Rec.)
Def.'s Ex. 519	149 Cong. Rec. S3,653-662 (daily ed. Mar. 13, 2003).	2003 WL 1093731 (Cong. Rec.)
Def.'s Ex. 520	149 Cong. Rec. H4,910-19, H4,922-953 (daily ed. June 4, 2003).	2003 WL 21282273 (Cong. Rec.) 2003 WL 21282279 (Cong. Rec.)
Def.'s Ex. 521	149 Cong. Rec. S 11,589-1, 601,S11,614-620 (daily ed. Sept. 17, 2003).	2003 WL 22143050 Cong. Rec.) 2003 WL 22143061 (Cong. Rec.)
Def.'s Ex. 522	149 Cong. Rec. H9,142-155 (daily ed. Oct. 2, 2003).	2003 WL 22271695 (Cong. Rec.)

Def.'s Ex. 523	149 Cong. Rec. S12,914-948 (daily ed. Oct. 21, 2003).	2003 WL 22399089 (Cong. Rec.) 2003 WL 22399091 (Cong. Rec.)
Def.'s Ex. 893	Partial-Birth Abortion Ban Act: House Committee Reports Index	N/A
Def.'s Ex. 894	Partial-Birth Abortion Act: Floor Debate Index	N/A
Def.'s Ex. 895	Partial-Birth Abortion Act: Index of Documents, Statements, and Letter from Doctors and Medical Organizations Reprinted in the Congressional Record	N/A
Def.'s Ex. 896	Partial-Birth Abortion Ban Act: Index of Speeches and Prepared Remarks of Members of Congress in the Congressional Record	N/A
Def.'s Ex. 897	145 Cong. Rec. S12,863-899, S12,904-920 (daily ed. Oct. 20, 1999). 145 Cong. Rec. S12,949-970, S12,972-999 (daily ed. Oct. 21, 1999)	1999 WL 957925 (Cong Rec.)1999 WL 957927 Cong. Rec.) 1999 WL 960679 (Cong. Rec.) 1999 WL 960681 (Cong. Rec.) 1999 WL 960683 (Cong. Rec.)
Def.'s Ex. 898	146 Cong. Rec. H1,771-1,801 (daily ed. Apr. 5, 2000).	2000 WL 349966 (Cong. Rec.)
Def.'s Ex. 899[176]	Bound Vol: 143 Cong. Rec. 8,209-229, 8319-382, 8,794-8,817 (1997). 144 Cong. Rec. 20,665-692, 20,883-896 (1998) Daily Ed.: 143 Cong. Rec. S4,431-451 (daily ed. May 14, 1997). 143 Cong. Rec. S4,517-575 (daily ed. May 15, 1997). 143 Cong. Rec. S4,694-4,716 (daily ed. May 20, 1997). 144 Cong. Rec. S10,474-499 (daily ed. Sept. 17, 1998). 144 Cong. Rec. S10,551-564 (daily ed. Sept. 18, 1998).	1997 WL 250191 (Cong Rec.) 1997 WL 252927 (Cong Rec.) 1997 WL 264645 (Cong Rec.) 1997 WL 264647 (Cong. Rec.) 1997 WL 264649 (Cong. Rec.) 1998 WL 636884 (Cong Rec.) 1998 WL 638990 (Cong. Rec.) 1998 WL 638991 (Cong. Rec.)

[176] Although bound editions of the congressional record are now available for the dates covered by Exs. 899-902, the exhibits received by this court were taken from daily editions. Because this opinion cites to the page numbers of the daily editions, this appendix provides the Bluebook citation for the daily edition as well as that for the bound volume.

Def.'s Ex. 900	Bound Vol.: 143 Cong. Rec. 4,388-4,429, 21,829-852 (1997). 144 Cong. Rec. 16,975-995 (1998). Daily Ed.: 143 Cong. Rec.H1,192-1,231 (daily ed. Mar. 20, 1997). 143 Cong. Rec. H8,640-663 (daily ed. Oct. 8, 1997). 144 Cong. Rec. H6,190-6,213 (daily ed. July 23, 1998).	1997 WL 125472 (Cong. Rec.) 1997 WL 125477 (Cong. Rec.) 1997 WL 617992 (Cong. Rec.) 1998 WL 412270 (Cong. Rec.) 1998 WL 412274 (Cong. Rec.) 1998 WL 412284 (Cong. Rec.) 1998 WL 412290 (Cong. Rec.) 1998 WL 412292 (Cong. Rec.)
Def.'s Ex. 901	Bound Vol.: 141 Cong. Rec. 31,539-561, 31-626-667, 31,670-72, 35,182-5,204, 35,309-319, 35,492-5,508, 35,845-892 (1995). 142 Cong. Rec. 24,975-25,000, 25,005-029 (1996). Daily Ed.: 141 Cong. Rec. S16,730-752 (daily ed. Nov. 7, 1995). 141 Cong. Rec. S16,761-6,801, S16,804-06 (daily ed. Nov. 8, 1995). 141 Cong. Rec. S17,881-7,903 (daily ed. Dec. 4, 1995). 141 Cong. Rec. S18,002-011 (daily ed. Dec. 5, 1995). 141 Cong. Rec. S18,071-086 (daily ed. Dec. 6, 1995). 141 Cong. Rec. S18,183-8,228 (daily ed. Dec. 7, 1995). 141 Cong. Rec. S11,337-361, S11,366-389 (daily ed. Sept. 26, 1996).	1996 WL 652739 (Cong. Rec.) 1996 WL 656011 (Cong. Rec.) 1996 WL 656014 (Cong. Rec.) 1996 WL 709778 (Cong. Rec.) 1996 WL 713546 (Cong. Rec.) 1996 WL 715975 (Cong. Rec.) 1996 WL 722593 (Cong. Rec.) 1996 WL 546653 (Cong. Rec.) 1996 WL 546667 (Cong. Rec.)
Def.'s Ex. 902	Bound Vol.: 141 Cong. Rec. 31,142-169 (1995). 142 Cong. Rec. 6,617-18, 6,632-673, 23,815-851 (1996). Daily Ed.: 141 Cong. Rec. H11,593-1,618 (daily ed. Nov. 1, 1995). 142 Cong. Rec. H2,895-2,929 (daily ed. Mar. 27, 1996). 142 Cong. Rec. H10,608-642 (daily ed. Sept. 19, 1996).	1996 WL 639915 (Cong. Rec.) 1996 WL 639916 (Cong. Rec.) 1996 WL 639917 (Cong. Rec.) 1996 WL 137032 (Cong. Rec.) 1996 WL 531092 (Cong. Rec.) 1996 WL 531093 (Cong. Rec.)

Appendix II

Judge's Summary Table of Individual Physicians' Statements to Congress

Name of Doctor	Claimed to Perform Abortions [17]	Claimed to Use the Banned Procedure or a Variant	Position on Ban	Board-Certified OB/GYN	Comments
Dr. Martin Haskell	Yes	Yes (including conversion to footling breech if necessary)	Opposed	No	Following Dr. McMahon, Dr. Haskell was the second to use the procedure. In information provided to a federal court that was placed in the record, Dr. Haskell stated that he had a complication rate of 2 per 1,000 operations for the standard D&E procedure and no complications for the banned procedure in 1,000 operations using the procedure.
Dr. Pamel Smith	No	No	Supported	Yes	President-Elect of American Association of Pro-Life Obstetricians and Gynecologists
Dr. J. Courtland Robinson	Yes	Unclear	Opposed	Unclear	Full-time OB/GYN faculty at Johns Hopkins School of Medicine.
Dr. Robert White	No	No	Probably supported	No	Gave statement regarding fetal pain.
Dr. Watson Bowes	No	No	Supported	Yes	OB/GYN Professor at University of North Carolina.
Dr. James McMahon	Yes	Yes (including conversion to footling breech if necessary	Opposed	No	Pioneered procedure. In information provided to Congress, he stated that he had used the procedure 2,000 times with 5 major complications.

[17] For purpose of this summary, I did not indicate that a physician performed abortions unless that physician specifically *claimed* to perform abortions when the fetus was living and as part of his or her normal practice when the doctor made his or her statements to Congress. Thus, some physicians are categorized as not performing abortions when, in fact, they do so. For example, in this table Dr. Creinin is listed as not claiming to do abortions. At trial, I learned that Dr. Creinin in fact does perform abortions. Nonetheless, the table accurately describes what Congress was told. I also followed the same protocol for the next category: "*Claimed to Use the Banned Procedure or a Variant.*"

Dr. Mary Campbell	Probably	Unclear	Opposed	Yes	Observed Dr. McMahon perform the banned procedure. Medical Director of Planned Parenthood of Metropolitan Washington.
Dr. Norig Ellison	No	No	Neutral	No	Gave testimony on impact of anesthesiology on fetuses.
Dr. Dru Elaine Carlson	No	No	Opposed	Unclear	Perinatologist and geneticist who referred patients to Dr. McMahon because of serious fetal anomalies.
Dr. Nancy Romer	No	No	Supported	Yes	Chair of OB/GYN Department at Dayton, Ohio, hospital
Dr. Warren Hern	Yes	Yes (but only on dead fetuses)	Opposed	Unclear	Author of leading textbook on abortion.
Dr. James Schreiber	No	No	Opposed	Probably	Professor and head of obstetrics and gynecology at Washington University Medical Center.
Dr. David Cromer	No	No	Opposed	Unclear	Member of the Department of Obstetrics and Gynecology at Evanston Hospital in Illinois.
Dr. Laurence Burd	No	No	Opposed	Unclear	Associate clinical professor of obstetrics and gynecology at the University of Illinois. Refers patients to a physician who performs the banned procedure. Believes the procedure is safe, necessary, and helpful for the determination of fetal abnormalities.

Dr. Antonio Scommegna	Unclear	Unclear	Opposed	Unclear	On staff at the University of Illinois at Chicago College of Medicine in the Department of Obstetrics and Gynecology. "[V]ividly recall[s]" a case where the banned procedure was necessary to avoid "spreading infection, affecting her future fertility and perhaps compromising her life."
Dr. Donald Sherline	Unclear	Unclear	Opposed	Unclear	On OB/GYN staff at Cook County Hospital. Holds the opinion that the banned procedure is "the safest method for the mother when carried out by an experienced operator," but also believes, on ethical grounds, that procedure should not be performed "except in the most demanding medically indicated situations."
Dr. Samuel Edwin	Unclear	Unclear	Opposed	Unclear	OB/GYN practitioner from Michigan. Holds the opinion that the "D&X procedure is the safest option" in medical emergencies.
Dr. L. Laurie Scott	No	No	Supported	Probably	Maternal-fetal medical specialist at University of Texas Southwest.
Dr. Margaret Nordel	No	No	Supported	Unclear	Practicing OB/GYN who holds the opinion that the procedure is "unnecessary to protect either the life or the health" of women.

Dr. Karen Shinn	No	No	Supported	Unclear	Practicing OB/GYN who holds the opinion that the procedure is "very dangerous and absolutely unnecessary."
Dr. William Rashbaum	Yes	Yes	Opposed	Probably	OB/GYN professor at Cornell School of Medicine and Albert Einstein College of Medicine. Has been using banned procedure "routinely" since 1979.
Dr. Herbert Jones	Yes	Yes	Opposed	Yes	Practitioner. Has needed to use the procedure two or three times.
Dr. David Birnbach	No	No	Probably supported	No	Gave testimony on anesthesiology.
Dr. David Chestnut	No	No	Probably supported	No	Gave testimony on anesthesiology.
Dr. Jean Wright	No	No	Probably supported	No	Gave testimony on anesthesiology.
Dr. Mitchell Creinin	No	No	Opposed	Unclear	Director of Family Planning at Magee-Women's Hospital.
Dr. Albert Corcoran	No	No	Supported	Unclear	OB/GYN practitioner. Thinks banned procedure is dangerous.

Dr. Curtis Cook	No	No	Supported	Yes	Founding member of Physicians Ad Hoc Coalition for Truth About Partial-Birth Abortion (PHACT).
Dr. Sheila Kuzmic	No	No	Supported	No	Pediatrician.
Dr. David Grimes	Yes	Yes	Opposed	Yes	Former Chief of the Department of Obstetrics, Gynecology, and Reproductive Sciences at San Francisco General Hospital; former Chief of Abortion Surveillance Branch of the Centers for Disease Control; gave an example of use of procedure, concluding that in that case "an intact D&E was the fastest and safest option available for me and to the patient."
Dr. C. Everett Koop	No	No	Supported	No	Former Surgeon General. Held the opinion that it was "never necessary" to perform an abortion on a viable fetus to preserve the health of the mother.
Dr. Kathi Aultman	No (although she did prior to 1983)	No	Supported	Yes	Member of Ethics Commission of Christian Medical and Dental Association.
Dr. Natalie Roche	Unclear	Unclear	Opposed	Unclear	OB/GYN professor at New Jersey Medical College.

Dr. Felicia Stewart	Unclear	No	Opposed	Unclear	Former Assistant Secretary for Population Affairs at Department of Health and Human Services; adjunct professor in the Department of Obstetrics, Gynecology and Reproductive Health Services and co-director of the Center for Reproductive Health Research and Policy at the University of California, San Francisco; former director of the Reproductive Health Program of the Henry J. Kaiser Family Foundation; opposed ban because she believed it would force women to have more dangerous procedures, most particularly hysterectomies.
Dr. Gerson Weiss	Unclear	Unclear	Opposed	Probably	Chair of Department of Obstetrics and Gynecology and Women's Health at New Jersey Medical College.
Dr. Mark Neerhof	No	No	Supported	Probably	On OB/GYN clinical faculty at Northwestern.

Dr. Phillip Darney	Yes	Yes	Opposed	Probably	Professor and Chief Obstetrics, Gynecology, and Reproductive Sciences at San Francisco General Hospital and the University at California, San Francisco. Responsible for department that performs 2,000 abortions a year. Gave two very case-specific examples of the need for and safety of the banned procedure.
Dr. Daniel Wechter	No	No	Supported	Yes	Disagreed with Dr. Darney.
Dr. Steve Calvin	Yes (although rarely)	Yes (but only to save the life of the woman)	Supported	Probably	Disagreed with Dr. Darney. Co-chair of Program in Human Rights in Medicine and professor at Minnesota.
Dr. Nathan Hoeldtke	No	No	Supported	Yes	Disagreed with Dr. Darney.
Dr. Bryon Calhoun	No	No	Supported	Yes	Disagreed with Dr. Darney.
Dr. T. Murphy Goodwin	No	No	Supported	Probably	Chief of Division of Maternal-Fetal Medicine at the University of Southern California. "Mindful of Dr. Darney's broad experience with surgical abortion," disagreed with Dr. Darney.
Dr. Susan Rutherford	No	No	Supported	Yes	Disagreed with Dr. Darney.
Dr. Camilia Hersh	No	No	Supported	Yes	Member of PHACT.
Dr. Lewis Marola	No	No	Supported	Unclear	Practitioner.

Dr. Vanessa Cullins	Probably	Unclear	Opposed	Yes	Vice-President of Medical Affairs for Planned Parenthood.
Dr. Anne Davis	Unclear	Unclear	Opposed	Yes	Clinical OB-GYN professor at Columbia University.

Appendix III

Judge's Summary Table of Physicians' Trial Testimony

Physician Performing Procedure	Types of Procedures Performed	Number of Procedures Performed	Gestational Age Procedures Performed	Induces Fetal Death Before Abortion	Frequency of Fetus Delivering Intact up to Head	Where Abortions Performed
Dr. Carhart	RU 486; vaccum aspiration; D&E; intentional intact D&E. Has performed abortions since 1988.	1,400 per year. 180 of those in second trimester, 5 of those for fetal anomalies.	Performs intact D&E as variant of D&E at 14-17 weeks. Elective abortions up to beginning of 23 weeks; up to end of 24 weeks for medical or psychological reasons unless fetus is viable.	Yes; 18 weeks and later.	4 to 6 times per year in patients between 13 and 18 weeks. 10% of patients over 20 weeks.	Clinic; abortions not allowed at area hospitals.
Dr. Fitzhugh	D&C; D&E; unintentional intact D&E. Has performed abortions since 1969.	70 per week in first trimester; 5-7 per week in second trimester.	Performs up to 20 weeks; occasionally later if fetus naturally dies prior to procedure.	No	2-3 times per year.	Seocnd-trimester abortions performed at hospital per state law.
Dr. Vibhakar	Medical abortions; suction curettage; D&E; induction.	264 in second trimester in 2001-2003; 10-20% of those for fetal or maternal indications.	Through 19 weeks at independent nonprofit clinic; up to 23 weeks at University of Iowa; up to 24 weeks to save life or health of mother.	No	1-2 times.	Independent nonprofit clinic & university hospital.

Dr. Knorr	D&C; RU 486 & methotrexate D&E; intentional intact D&Es in second trimester in rare instances. Has performed abortions since early 1980s.	5,000-6,000 in 2003. 12-15% in second trimester.	Up to 24 weeks.	Very rarely; if so, after 22 weeks.	10 times per year in patients from 20-24 weeks; much less than that for 16-20 weeks.	Private offices
Dr. Howell	Has never performed or observed an abortion.	N/A	N/A	N/A	N/A	N/A
Dr. Mazariegos	Has never performed an abortion; has observed less than 5 first-trimester abortions in medical school.	N/A	N/A	N/A	N/A	N/A

Dr. Bowes	D&C for incomplete miscarriages; suction curettage; D&E; induction of labor for fetal death; supervised induction abortions on live fetuses.	Supervised "some number" of induction abortions on live fetuses in both the first and second trimesters. Over the course of his career, supervised or assisted in performing D&Es on live fetuses in two or three cases. Performed or supervised 150 total procedures on demised fetuses, with the majority of those being inductions and the remainder supervision of D&Es.	First and second trimesters.	Saline & urea used in induction abortions cause fetal demise prior to induction. Has never injected fetal heart with substance to cause fetal demise.	Unclear	Some at University of Colorado and University of North Carolina.
Dr. Anand	Has never performed an abortion procedure.	N/A	N/A	N/A	N/A	N/A
Dr. Sprang	D&C; D&E induction in cases of fetal demise only. Has never performed intact D&E.	450-600 miscarriages in all trimesters. Aborted one live fetus during hysterotomy to save life of mother.	D&C up to 14 weeks; D&E up to 17 weeks; inductions for fetal demise up to 40 weeks.	N/A	N/A	Hospital

Dr. Lockwood	Dilation & aspiration or suction curettage; medical inductions. No abortions on live fetuses.	Observed 10 D&Es up to 20 weeks during residency; 3-4 per year during fellowship; 1-2 per year at Mt. Sinai, NYU & Yale. Medical inductions on non living fetuses 40 times during residency & continues to do so.	Dilation & aspiration or suction curettage after fetal death up to 12-13 weeks	N/A	N/A	N/A
Dr. Doe	Suction curettage; manual vacuum aspiration; D&E; intentional intact D&E in some cases.	1,130 abortions in 2003; 958 abortions in 2002; 940 abortions in 2001.	Suction curettage & manual vacuum aspiration in first trimester. D&E in second trimester.	No in fetal-indication cases. Yet in maternal-indication cases at 18 weeks and after.	In 2003, 35 fetuses delivered intact, at least to the head.	Sealed information.
Dr. Baergen	Not identified. No experience with D&X.	A "few [abortion] procedures" as intern in 1983 & 1984. None over past 20 years.	N/A	N/A	N/A	N/A

Dr. Chasen	D&C; D&E; D&X; induction abortions.	Total of 500; 200-300 D&C's; 200-300 D&Es; 50-75 D&X's. Supervised 50 second-trimester abortions over past year. D&E is only method of second-trimester abortion performed over last year.	D&C before 14th week. D&E from 13 to 23 weeks and 6 days (and possibly later in cases in fetal demise)	Some times. If yes, injects KCl into fetal heart.	12 times per year.	Clinic at the New York Weill/Cornell Medical Center.
Dr. Cook	Suction curettage for spontaneous miscarriage; D&Es after fetus demised in "rare instances"; no D&E on live fetuses; medical induction. No elective abortions.	D&Es on demised fetuses once per year or less (performed 3-5 himself & supervised under 20 in his career). Inductions for fetuses less than 23 weeks 1-2 times per month. Inductions after 23 weeks once per week.	Suction curettage up to 12 weeks; medical induction after 16 weeks.	Has never used digoxin or KCl to induce fetal demise in performing medical inductions.	Unclear	Unclear' presumably hospital.

Dr. Shadigian	D&C; D&E; medical induction of labor, primarily on expired fetuses. Has observed D&C's and D&Es on live fetuses.	"Hundreds" of D&Cs on expired fetuses. Helped with 30-50 D&Es on expired fetuses during residency; performed 10-20 D&Es on expired fetuses since 1994. Has induced labor for live fetuses 20-40 times in career in situations where mother would die if pregnancy not terminated. Medical induction performed weekly prior to term; it is "more rare" to use induction prior to viability.	D&Cs during 5th to 12th week; D&Es during second trimester. Performed 8 to 10 D&Es on 17-to 19-week fetuses at University of Michigan and on 20-week fetuses during residency. Medical induction most common 20 weeks and up.	No	Unknown	University of Michigan

Dr. Broekhuizen	D&C; second-trimester D&E; second trimester induction abortions.	D&Es and induction abortions are "regular" part of practice for past 20 years. 400-500 D&Es over career, with 90 to 95% involving dismember-ment. Total number of inductions unknown, but more inductions than D&Es.	D&Es up to 20 weeks. Induction up to 24 weeks, the legal limit in Wisconsin. Inductions past 24 weeks only in cases of lethal fetal anomalies.	30-40 total times by injecting digoxin into amniotic fluid in induction abortions. Never with D&Es.	Unclear	D&Es on outpatient basis at hospital. Unless completed within 23 hours, medical induction abortion is inpatient hospital procedure.
Dr. Frederiksen	D&C; D&E; intentional intact D&E; medical induction.	Thousands of D&Es over career; approximate-ly 100-125 per year.	23 and 5/7 weeks for elective abortions. Has performed induction abortions at 20 to 24 weeks. After 24 weeks, only induction for lethal fetal anomalies.	Yes, for labor induction with misoprostol. Injects digoxin or KCl into fetal heart. No for D&Es, except at woman's specific request.	Unknown	Hospital
Dr. Creinin	Medical abortions; D&C; D&E intact D&E. No induction abortions for past 10 years.	5,000 over career; 500 per year. Has performed 3 intact D&Es, as defined by ACOG, over career.	Medical abortions through 9 weeks; D&Cs through 14 or 15 weeks; D&Es from 14 to 15 weeks through 23 and 6/7 weeks (limited to 56 millimeters biparietal diameter).	No	50 times in career.	Planned Parenthood clinic up to 18 weeks. Hospital at 18 weeks and beyond.

Dr. Westhoff	Medical abortions; D&C; labor induction (in the past); D&E, including intact D&E.	Several thousand abortions since 1978. Several hundred labor inductions over career; 400 out of 500 second-trimester abortions were by induction in 1997; since Special GYN Services opened in 2001, refers labor-induction cases. 750 D&Es (including intact D&Es) in 2001-2003.	Medical abortions up to 9 weeks. D&Cs up to 12 or 13 weeks. D&Es 14 weeks through 23 and 6/7 weeks. Intact D&E more common after 18 to 20 weeks through 23 and 6/7 weeks.	No.	Unclear	Hospital and unidentified facility with operating rooms and access to general anesthesia.
Dr. Paul	Medical abortions; D&C; D&E, including intact D&E.	Unknown	D&Es up to 18 and 6/7 weeks, although trained in residency to perform D&Es up to 23 weeks.	Unknown	"1 to 10 to 1 to 20"	Planned Parenthood outpatient clinics.

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Dr. Clark	D&C; labor induction; dismember-ment D&E. Never performed intact D&E. Abortion done only when medically necessary. Has "read about" the intact D&E, but has never seen one being performed.	12 first-trimester abortions on live fetuses; less than 20 labor-induction abortions; 12 D&Es on live fetuses. In cases of spontaneous abortion (miscarriage or demised fetus), hundreds of procedures, with D&C and labor induction the most common.	D&Cs in first trimester; D&Es never beyond 20 weeks; labor induction to term.	No	Never	Unknown
Dr. Hammond	Medical abortion; D&C; labor induction; D&E, including intact D&E.	Has performed abortions for 15 years; at least 3,000 total performed, with 1,000 of those being D&Es. At 20 to 24 weeks, 96% are D&Es and remainder are labor induction.	24 weeks is latest gestational age procedures are performed.	No	In half of D&Es at 20-24 weeks, Dr. Hammond is able to remove the fetus intact to the level of the fetal navel or above. Fetus delivers intact to level of calvarium at least 3 times per month.	Hospital

Dr. Cain	D&E; labor induction; hysterectomy for cervical carcinoma; hysterectomy. Has never performed intact D&E or other elective abortion.	Less than 25 D&Es over career; less than 5 inductions over career; 1 hysterotomy; less than 10 hysterectomies	Unknown	Unknown	Unknown	Unknown

Appendix IV

Exhibits Received for Limited Purpose

Ex. 3, Press Release, American College of Obstetricians and Gynecologists [hereinafter ACOG], *Statement on So-Called "Partial Birth Abortion" Law* (Oct. 3, 2003) (stating that "intact D & X 'may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman'").

Ex. 4, Statement, ACOG, *The American College of Obstetricians and Gynecologists On the Subject of "Partial-Birth Abortion" Bans* (July 8, 2002) (opposing the ban "as an inappropriate, ill-advised and dangerous intervention into medical decision making").

Ex. 5, Statement, ACOG Executive Board, *Statement of Policy: Abortion Policy* (Sept. 2000) (stating that "[t]erminating a pregnancy is performed in some circumstances to save the life or preserve the health of the mother[,]" and "[i]ntact D & X is one of the methods available in some of these situations . . . ACOG could identify no circumstances under which this procedure . . . would be the only option to save the life or preserve the health of the woman. An intact D & X, however, may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman, and only the doctor . . . can make this decision.").

Ex. 6, Statement, ACOG Executive Board, *Statement of Policy: Statement on Intact Dilation and Extraction* (Jan. 12, 1997) (same).

Ex. 7, ACOG, *Fact Sheet on the January 1997 ACOG Policy Statement Regarding Intact Dilation and Extraction* (Apr. 4, 1997) (elaborating on and re-

sponding to possible concerns about ACOG's policy position, stating in reference to safety that "ACOG is unaware of any comparative maternal morbidity studies specifically evaluating Intact D & X procedures with other methods of abortion. However, . . . other data have shown that second trimester instrumental abortion is safe.").

Ex. 9, ACOG Technical Bulletin No. 109, *Methods of Midtrimester Abortion* (Oct. 1987) (concluding that "[d]ata suggest that D & E may be faster, safer, and more acceptable to patients than induction of labor").

Ex. 11, ACOG Executive Board Minutes at 4 & 19 (Jan. 11-13, 1997) (noting internal ACOG board discussions over a "Statement on Intact Dilations and Extraction" and revisions of that statement).

Ex. 13, Letter from Dr. Seward (Vice President, American Medical Association) to Sen. Santorum of 5/19/97 (expressing AMA support for HR 1122 due to its incorporation of an exception to save the life of the mother, the clear definition of the procedure within the bill, and the right of the accused physician to have his or her conduct reviewed by the State Medical Board prior to a criminal trial), with attached AMA Board of Trustees Report 26-A-97, presented by Dr. Dickey (June 1997) (presenting medical, legal, and ethical perspectives on abortion).

Ex. 14, Letter from Dr. Epstein (President, American Medical Women's Association) to Rep. Nadler of 3/25/03 (opposing ban as "an inappropriate intervention in the decision-making relationship between physician and patient" and as an imprecise bill that "may ultimately undermine the legality of other techniques . . . used in . . . abortion and non-abortion situations").

Ex. 15, Letter from Dr. Silva (American Medical Women's Association) to Rep. Chabot of 7/18/02 (same).

Ex. 16, Memorandum from American Medical Women's Association to John Ashcroft of 12/19/03 (same).

Ex. 17, Letter from Dr. Benjamin (Executive Director, American Public Health Association) to House of Representatives of 3/31/03 (opposing the ban because "restrictions to safe, medically accepted abortion procedures severely jeopardize women's health and well-being[,]" and because "it fails to include adequate health exception language").

Ex. 18, American Public Health Association, *Opposition to Constitutional Amendments or Statutes to Prohibit Abortion* (1981), *available at* http://www.apha.org/legislative/policy/policysearch/index.cfm?fuseaction=view&id=976 (opposing any restriction on the provision of safe and legal abortion services).

Ex. 18, American Public Health Association, *Safeguarding the Right to Abortion as a Reproductive Choice* (1989), *available at* http://www.apha.org/legislative/policy/policysearch/index.cfm?fuseaction=view&id=1180 (reaffirming APHA commitment to legal right of women to accessible, affordable, and safe abortion services).

Ex. 19, Amy M. Autry, et al., *A comparison of medical induction and dilation and evacuation for second-trimester abortion*, 187 Am. J. Obstet. & Gynecol. 393 (2002) (concluding that overall complication rate was significantly lower in patients who underwent dilation and evacuation than in patients who underwent medical induction).

Ex. 20, Nancy J. Binkin, *Trends in Induced Legal Abortion Morbidity and Mortality*, 13 Clinics in Obstet. & Gynecol. 83 (1986) (attributing declining abortion mortality rates in the United States to a "downward shift in the gestational ages at which abortions are obtained and the increased use of D & E for abortions at 12 gestational weeks or later").

Ex. 21, Trude A. Bennett, et al., *Pregnancy-associated hospitalizations in the United States in 1991 and 1992: A comprehensive view of maternal morbidity*, 178 Am. J. Obstet. & Gynecol. 346 (1998) (concluding that because of under-reporting and changes in medical care, recent declines in maternal hospitalization may not represent true reductions in maternal morbidity).

Ex. 22, William M. Callaghan & Cynthia J. Berg, *Pregnancy-Related Mortality Among Women Aged 35 Years and Older, United States, 1991-1997*, 102 Obstet. & Gynecol. 1015 (2003) (concluding that "[r]ecognition of the risk of death borne by older pregnant women is needed to inform their care").

Ex. 24, Willard Cates, et al., *The Public Health Impact of Legal Abortion: 30 Years Later*, 35 Persp. on Sexual & Reprod. Health 25 (2003) (finding that since *Roe v. Wade* there has been a reduction in abortion-related complications and deaths).

Ex. 25-26, Stephen Chasen, et al., *Dilation and evacuation at ≥20 weeks: Comparison of Operative techniques* (2004) (draft versions one and two; draft one concluding that "[d]ilation and evacuation with intact extraction is as safe as dilation and extraction with disarticulation after 20 weeks' gestation"; draft two concluding that "[o]utcomes appear similar between pa-

tients undergoing dilation and evacuation and intact dilation and extraction after 20 weeks' gestation").

Ex. 27, Stephen Chasen, et al., *Dilation and Evacuation at ≥20 Weeks: Comparison of Operative Techniques*, 190 Am. J. Obstet. & Gynecol. 1180 (2004) (concluding that "[o]utcomes appear similar between patients undergoing dilation and evacuation and intact dilation and extraction after 20 weeks' gestation").

Ex. 28, Stephen Chasen, et al., Data Chart (representing underlying data for Chasen publication, *supra* at Ex. 27).

Ex. 30, Letter from Cornell Univ. Med. Coll. Inst'l Review Bd. to Dr. Chasen of 3/20/03 (approving protocol for study in Chasen publication, *supra* at Ex. 27).

Ex. 34, Centers for Disease Control and Prevention [hereinafter CDCP], *Pregnancy-Related Mortality Surveillance-United States, 1991-1999*, 52 Morbidity & Mortality Wkly. Rep. 1 (2003) (finding that reported pregnancy mortality rate substantially increased during 1991-1999, probably because of improved ascertainment of pregnancy-related deaths).

Ex. 36, Isabella Danel, et al., *Magnitude of Maternal Morbidity During Labor and Delivery: United States, 1993-1997*, 93 Am. J. Pub. Health 631 (2003) (finding 43% of women experienced some type of adverse complication during labor and delivery).

Ex. 41, Janet E. Gans Epner, et al., *Late-term Abortion*, 280 JAMA 724 (1998) (finding that mortality and morbidity rates for D & E are lower than for labor induction, hysterotomy, and hysterectomy, but the rates between D & E and induction become similar after 20 weeks of gestation).

Ex. 44, David A. Grimes, et al., *Mifepristone and misoprostol versus dilation and evacuation for mid-trimester abortion: a pilot randomised controlled trial,* 111 Brit. J. Obstet. & Gynecol. 148 (2004) (study comparing D & E with induction stopped after one year because most women participating chose D & E abortions rather than allowing the method to be randomly selected).

Ex. 45, David A. Grimes, *The Continuing Need for Late Abortions,* 280 JAMA 747 (1998) (discussing evidence that D & E is safer than induction, and proposing that intact D & E could be "useful in the presence of fetal anomalies, such as hydrocephalus").

Ex. 50, Warren M. Hern, *Abortion Practice,* ch. 5, at 101-60 (J.B. Lippincott Co.1990) (describing operative procedures and techniques for first- and second-trimester abortions, no specific mention made of intact D & E).

Ex. 51, Hugh L. Hodge, *The Principles and Practice of Obstetrics* 231-73 (Henry C. Lea 1866) (textbook with chapter discussing craniotomy, "the most ancient of obstetric operations." "Delivery by this operation implies perforation of the head, diminution of its size, and then its deliverance.").

Ex. 58, Herschel W. Lawson, et al., *Abortion mortality, United States, 1972 through 1987,* 171 Am. J. Obstet. & Gynecol. 1365 (1994) (finding that before 1977 infection and hemorrhage were the leading causes of abortion-related deaths, but since 1983 anesthesia complications have been the most frequent causes).

Ex. 59, Herschel W. Lawson, et al., *Abortion Surveillance, United States, 1984-1985,* 38 Morbidity & Mortality Wkly. Rep. 11 (1989) (reporting that abortion

mortality rates remained stable between 1984 and 1985).

Ex. 64, James T. McMahon, *Intact D & E: The First Decade* (presented April 2, 1995, to National Abortion Federation Conference) (describing technique of intact D & E and the comparative costs/benefits of intact D & E with those of classical D & E).

Ex. 70, Maureen Paul, et al., *A Clinician's Guide to Medical and Surgical Abortion* 39-89, 107-167, 197-228 (Churchill Livingstone 1999) (textbook describing technique of intact D & E, along with other abortion techniques).

Ex. 73, D. Schneider, et al., *Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation*, 88 Obstet. & Gynecol. 412 (1996) (finding that late second-trimester termination by laminaria dilation and evacuation is safe and probably not associated with future adverse pregnancy outcomes).

Ex. 74, Lee P. Shulman, *Dilation and Evacuation for Second-Trimester Genetic Pregnancy Termination*, 75 Obstet. & Gynecol. 1037 (1990) (stating that D & E carries morbidity and mortality rates significantly lower than labor induction, but labor induction is the most commonly used method for genetic terminations, probably because it produces an intact fetus which may more consistently confirm genetic abnormalities, and arguing that "D & E is reliable in confirming most prenatal diagnoses and should be the procedure of choice when second-trimester pregnancy termination is chosen because of fetal abnormalities.").

Ex. 110, Uriel Elchalal, et al., *Maternal Mortality Following Diagnostic 2nd-Trimester Amniocentesis*, 19 Fetal Diagnosis & Therapy 195 (2004) (presenting two

cases of maternal mortality after transabdominal amniocentesis).

Ex. 536, Kanwaljeet S. Anand & Bonnie Taylor, *Consciousness and the Fetus*, Bioethics Newsletter 2 (Am. Acad. Pediatrics, Elk Grove Village, Ill., Jan. 1999) (suggesting that the human fetus may perceive pain, which should be alleviated during fetal surgery or late abortion).

Ex. 537, K.J.S. Anand, et al., *Consciousness, Behavior, and Clinical Impact of the Definition of Pain*, 8 Pain Forum 64 (1999) (arguing that the current definition of pain is flawed in that it relies too much on linguistic evidence of the subjective experience of pain).

Ex. 538, K.J.S. Anand & Mervyn Maze, *Fetuses, Fentanyl, and the Stress Response: Signals from the Beginnings of Pain?*, 95 Anesthesiology 823 (2001) (suggesting that the human fetus may perceive pain, which should be alleviated during fetal surgery or late abortion).

Ex. 539, K.J.S. Anand & Kenneth D. Craig, *Editorial: New perspectives on the definition of pain*, 67 Pain 3 (1996) (same).

Ex. 540, K.J.S. Anand, et al., *Pain and its Effects in the Human Neonate and Fetus*, 317 New Eng. J. Med. 1321 (1987) (concluding that pain pathways and cortical centers necessary for pain perception are well developed late in gestation of human fetuses, although the data does not prove that fetuses subjectively experience pain as older children and adults do).

Ex. 543, John Aucar, *Editorial Forward: Art, science and craftwork: the role of evidence in surgery*, 1 Evidence-Based Surgery 1 (1999) (editor's comment introducing a new journal devoted to discussing the ways

various types of evidence can inform and advance surgical techniques).

Ex. 544, B.M. Audu, et al., *Diagnostic features of cervical incompetence among women in Maiduguri*, 23 J. Obstet. & Gynaecol. 130 (2003) (in a review of 146 cases of cervical cerclage, 80% of the women had a history of previous midtrimester (spontaneous or otherwise) abortions, and 5% of the women had a history of induced abortions).

Ex. 548, Adnan T. Bhutta & K.J.S. Anand, *Vulnerability of the developing brain neuronal mechanisms*, 29 Clinics in Perinatology 357 (2002) (proposing that two primary mechanisms lead to enhanced neuronal cell death in neonatal brains: excitotoxicity resulting from repetitive or prolonged pain, and enhanced neuronal apoptosis due to multiple metabolic stresses or lack of social stimulation).

Ex. 552, Ronald A. Chez, *Cervical Ripening and Labor Induction After Previous Cesarean Delivery*, 38 Clinical Obstet. & Gynecol. 287 (1995) (finding that the preponderance of published data on pregnant women attempting a vaginal birth after previous cesarean indicates that if there is no contraindication to spontaneous cervical ripening, there is no contraindication to use of prostaglandin gel or tents to achieve ripening and there is no contraindication to use of oxytocin or amniotomy to induce labor if there is no contraindication to the spontaneous onset of labor).

Ex. 555, Volkan Coskun & K.J.S. Anand, *Development of supraspinal pain processing, in Pain in Neonates* 23-54 (Elsevier Science B.V. 2d ed. 2000) (finding that data support the conclusion that the pain system undergoes a major reorganization during the perinatal

period of life, and that the onset of inhibitory supraspinal processing is a critical component required for the emergence of specific pain behaviors).

Ex. 556, A.D. Craig, *A new view of pain as a homeostatic emotion*, 26 Trends in Neurosciences 303 (2003) ("findings indicate that the human feeling of pain is both a distinct sensation and a motivation-that is, a specific emotion that reflects homeostatic behavioral drive, similar to temperature, itch, hunger and thirst").

Ex. 558, Philip D. Darney & R.S. Sweet, *Routing Intraoperative Ultrasonography for Second Trimester Abortion Reduces Incidence of Uterine Perforation*, 8 J. Ultrasound in Med. 71 (1989) (study of D & E second-trimester abortions showed "[t]he routine intraoperative use of ultrasonographic imaging to guide intrauterine forceps during uterine evacuation . . . resulted in a significant reduction in uterine perforation, the rate declining from 1.4% to .2%.").

Ex. 560, Eleanor A. Drey, et al., *Safety of intra-amniotic digoxin administration before late second-trimester abortion by dilation and evacuation*, 182 Am. J. Obstet. & Gynecol. 1063 (2000) (concluding that intra-amniotically administered digoxin may be considered safe for use before late second-trimester pregnancy termination for some, but not all, patients).

Ex. 563, Nicholas M. Fisk, et al., *Effect of Direct Fetal Opioid Analgesia on Fetal Hormonal and Hemodynamic Stress Response to Intrauterine Needling*, 95 Anesthesiology 828 (2001) (concluding that direct administration of fentanyl blunts the fetal stress response to intrauterine needling).

Ex. 564, Maria Fitzgerald, *Spontaneous and evoked activity of fetal primary afferents in vivo*, 326 Nature

603 (1987) (finding repeated stimulation of fetuses caused "long-lasting increases of both background and evoked activity. Such sensory input is likely to have a considerable influence on fetal movements and on the development of spinal cord connections.").

Ex. 566, Xenophon Giannakoulopoulos, et al., *Fetal plasma cortisol and B-endorphin response to intrauterine needling*, 344 Lancet 77 (1994) (finding data suggesting that the fetus mounts a hormonal stress response to invasive procedures, which raises the possibility that the human fetus feels pain *in utero*, and may benefit from anesthesia or analgesia for invasive procedures).

Ex. 567, Xenophon Giannakoulopoulos, et al., *Human Fetal and Maternal Noradrenaline Responses to Invasive Procedures*, 45 Pediatric Res. 494 (1999) (study results indicate that the fetus is capable of mounting an independent noradrenaline stress response to a needle transgressing its trunk from 18 weeks of gestation).

Ex. 570, Rachel Gitau, et al., *Fetal Hypothalamic-Pituitary-Adrenal Stress Responses to Invasive Procedures Are Independent of Maternal Responses*, 86 J. Clinical Endocrinology & Metabolism 104 (2001) (study results indicate a correlation between fetal and maternal cortisol levels, but not between fetal and maternal *B*-endorphin levels, suggesting cortisol transfer across the placenta, and fetal *B*-endorphin responses were apparent from 18 weeks of gestation and were independent of gestational age, whereas fetal cortisol responses were apparent from 20 weeks of gestation and were dependent on gestational age).

Ex. 574, Patricia S. Goldman-Rakic, *Development of Cortical Circuitry and Cognitive Function*, 58 Child Development 601 (1987) (finding that anatomical tracing in primate fetuses indicates various classes of cortical connections begin to form by the second trimester of pregnancy).

Ex. 577, David A. Grimes & Kenneth F. Schulz, *Morbidity and Mortality from Second-Trimester Abortions*, 30 J. Reprod. Med. 505 (1985) (concluding that D & E appears to be the safest method of second-trimester abortion available in the United States).

Ex. 585, Laurence Henriet & Monique Kaminski, *Impact of induced abortions on subsequent pregnancy outcome: the 1995 French naticnal perinatal survey*, 108 Brit. J. Obstet. & Gynecol. 1036 (2001) (study suggests a history of induced abortion increases the risk of preterm delivery, but more studies are needed to understand the roles of surgical versus medical abortion techniques).

Ex. 586, Peter G. Hepper, *The beginnings of mind-evidence from the behavior of the fetus*, 12 J. Reprod. & Infant Psychol. 143 (1994) (study of the prenatal ontogenesis of behavior suggests "that the mind will emerge in an immature form and that stimulation received *in utero*, and the behavior emitted, will play an important role in its development").

Ex. 590, International Association for the Study of Pain, *IASP Pain Terminology* (Feb. 13, 2004), *available at* http://www.iasp-pain.org/terms-p.html (providing definitions for terms related to pain).

Ex. 596, Robin B. Kalish, et al., *Impact of midtrimester dilation and evacuation on subsequent pregnancy outcome*, 187 Am. J. Obstet. & Gynecol. 882

(2002) (finding that second-trimester D & E is not a risk factor for midtrimester pregnancy loss or spontaneous preterm birth, and that preterm delivery in future gestations appears less likely when greater preoperative cervical dilation is achieved with laminaria, possibly because of a decrease in cervical trauma).

Ex. 598, Hannah C. Kinney, et al., *Three-Dimensional Distribution of 3H-Naloxone Binding to Opiate Receptors in the Human Fetal and Infant Brainstem*, 291 J. Comp. Neurology 55 (1990) (finding that by midgestation the regional distribution of 3H-naloxone binding in human fetuses is similar, but not identical, to that in infants).

Ex. 599, Ernest A. Kopecky, et al., *Fetal response to maternally administered morphine*, 183 Am. J. Obstet. & Gynecol. 424 (2000) (study provides evidence that morphine transfer across the human placenta significantly affects some components of the fetus's biophysical profile score).

Ex. 607, Martin F. McKneally & Abdallah S. Daar, *Introducing New Technologies: Protecting Subjects of Surgical Innovation and Research*, 27 World J. Surgery 930 (2003) (noting that most important advances in the history of medicine "were introduced through an informal, unregulated innovation process that has been enormously productive but can lead to ratification of ineffective or harmful treatment" and suggesting a "surgical innovation ethics paradigm that is a more nimble, flexible source of institutional and public oversight").

Ex. 609, Neena Modi & Vivette Glover, *Fetal pain and stress, in Pain Research and Clinical Management* 217-227 (Elsevier Science B.V. 2d ed. 2000) (stat-

ing that "[a]lthough there is not enough evidence to be certain, given the possibility that pain perception might be present in the fetus during the second trimester, it is reasonable to consider analgesia or anesthesia during potentially painful procedures from this time").

Ex. 610, Mark E. Molliver, et al., *The development of synapses in cerebral cortex of the human fetus*, 50 Brain Res. 403 (1991) (reporting presence of cortical synapses detected in a fetus at 8.5 weeks of gestation).

Ex. 612, Carl-Joachim Partsch, et al., *The Steroid Hormonal Milieu of the Undisturbed Human Fetus and Mother at 16-20 Weeks Gestation*, 73 J. Clinical Endocrinology & Metabolism 969 (1991) (study shows several important steroid hormones are actively secreted by fetus independently of the mother at 16-20 weeks of gestation).

Ex. 618, Angelique M. Reitsma & Jonathan D. Moreno, *Ethical Regulations for Innovative Surgery: The Last Frontier?*, 194 J. Am. Coll. Surg. 792 (2002) (suggesting that the current system of definitions, ethical theories, and voluntary professional guidelines may be inadequate to meet the challenge of surgical innovation).

Ex. 624, Lee P. Shulman & Sherman Elias, *Second-Trimester Pregnancy Termination by Dilation and Evacuation After Detection of Fetal Abnormalities*, 1 J. Women's Health 255 (1992) (concluding that D & E performed by experienced physicians is reliable for confirming most prenatal diagnoses and should be offered to women who elect to terminate pregnancies in the second trimester because of fetal abnormalities).

Ex. 625, Richard P. Smith, et al., *Pain and stress in the human fetus*, 92 Eur. J. Obstet. & Gynecol. & Re-

prod. Biology 161 (2000) (noting that it is not known if the fetus feels pain, but from 18-20 weeks the fetus does mount significant stress hormonal and circulatory changes in response to invasive procedures, but finding the optimal drug, dose, and route of administration of fetal anesthesia remains to be determined).

Ex. 627, Steven M. Strasberg & Philip A. Ludbrook, *Who Oversees Innovative Practice? Is There a Structure that Meets the Monitoring Needs of New Techniques?*, 196 J. Am. Coll. Surg. 938 (2003) (discussing the unexpected harm to patients that can come from seemingly safe surgical innovations, the lack of a formal compulsory regulatory system overseeing some categories of innovative procedures, and proposing solutions).

Ex. 629, Jeronima Teixeira & Roberto Fogliani, *Fetal haemodynamic stress response to invasive procedures*, 347 Lancet 624 (1996) (letter to the editor claiming to have shown that the fetus mounts a stress-hormone response to invasive procedures that transgress the fetal trunk).

Ex. 630, Jeronima Teixeira, et al., *Acute cerebral redistribution in response to invasive procedures in the human fetus*, 181 Am. J. Obstet. & Gynecol. 1018 (1999) (study shows that invasive procedures involving transgression of the fetal body are associated with a fetal hemodynamic stress response that is consistent with redistribution of blood supply to the brain).

Ex. 631, John M. Thorp, et al., *Long-term Physical and Psychological Health Consequences of Induced Abortion: Review of the Evidence*, 58 Obstet. & Gynecol. Surv. 67 (2002) (finding that induced abortion is a risk factor for placenta previa, subsequent preterm delivery, and mood disorders).

Ex. 633, Sampsa Vanhatalo & Onno van Nieuwenhuizen, *Fetal pain?*, 22 Brain & Dev. 145 (2000) (concluding that "it is not reasonable to speculate on the possible emotional experiences of pain in fetuses or premature babies. A clinically relevant aim is rather to avoid and/or treat any possibly noxious stimuli, and thereby prevent their potential adverse effects on the subsequent development.").

Ex. 635, M.P. Ward Platt, et al., *The ontogeny of the metabolic and endocrine stress response in the human fetus, neonate and child*, 15 Intensive Care Med. S44 (1989) (finding evidence of an endocrine and metabolic response to stress from the midtrimester of fetal life).

Ex. 637, F.G. Cunningham, et al., *Techniques for breech delivery, in Williams Obstetrics* (19th ed., Appleton & Lange) (describing and diagraming various techniques and positions of breech delivery).

Ex. 647, American College of Surgeons, *Statement on Emerging Surgical Technologies and the Evaluation of Credentials, reprinted from* 79 Bull. Am. Coll. Surgeons 40-41 (1994), *available at* http://www.facs.org/fellows_info/statements-18.html (outlining guidelines for evaluating the safety, efficacy, and costs of potentially important new surgical procedures, and for evaluating credentials of individuals for the purpose of awarding surgical privileges in new technologies).

Ex. 648, American College of Surgeons, *Statement on Issues to Be Considered Before New Surgical Technology is Applied to the Care of Patients, reprinted from* 83 Bull. Am. Coll. Surgeons 46-47 (1995), *available at* http://www.facs.org/fellows_info/statements/st-23.html (stating that evaluation of the value and safety of new biomedical technology to patients should include

comparisons with proven technologies, and qualifications of those who propose to use the new technology must be carefully assessed).

Ex. 655, ACOG, *Statement on Intact Dilation and Extraction* (unpublished, undated draft) (stating that intact D & X is one method available when termination of a pregnancy is indicated to save the life or preserve the health of the mother, but an ACOG panel could identify no circumstance under which it would be the only method).

Ex. 656, Letter from Pres. Clinton to Dr. Hale of 7/3/96, attaching Statement from Pres. Clinton to the House of Rep. of 4/10/96 (stating that he would not approve H.R. 1833 in part because he had heard from women who "were devastated to learn that their babies had fatal conditions . . . who were advised by their doctors that this procedure was their best chance to avert the risk of death or grave harm which, in some cases, would have included an inability to ever bear children again").

Ex. 657, Letter from Dr. Grimes to Sen. Byrd of 11/30/95 (stating in response to specific questions that the proposed banned procedure is "in reality, an old obstetric procedure" used for centuries called "internal podalic version" followed by "total breech extraction," that many fetal genetic defects are difficult to detect prior to 16 weeks of gestation, and that a fetus cannot feel pain as adults perceive it).

Ex. 658, Statement, ACOG, *Later Abortions: Questions and Answers* (undated) (giving ACOG position on why it opposes the ban).

Ex. 659, Statement, National Abortion Federation, *Third-Trimester Abortion: The Myth of "Abortion on*

Demand" (June 14, 1995) (stating that the "D & X procedure that opponents of choice want to ban is often the safest available for late abortions").

Ex. 660, National Abortion Federation, *Fact Sheet: Abortion After Twelve Weeks* (Oct. 1992) (stating that early abortions are the safest, but some abortions after 12 weeks are unavoidable).

Ex. 661, Martin Haskell, *Dilation and Extraction for Late Second Trimester Abortion, presented at* National Abortion Federation Risk Management Seminar (Sept. 13, 1992) (describing the procedure, the range of patients for which it may be appropriate, and some advantages and disadvantages of the technique).

Ex. 662, Wisconsin Right to Life Education Fund, *The D & X Abortion Procedure: Scientific Advancement or Human Rights Abuse?* (undated) (leaflet showing diagram of procedure).

Ex. 663, Allan Rosenfield, *Congress Plays Doctor*, N.Y. Times, April 1, 1996 (editorial) (stating that the anguished decision to use dilation and extraction is usually reached when a woman's life or health would be jeopardized if the pregnancy is continued or if there is a fetal abnormality incompatible with life).

Ex. 664, *Abortion Politics*, N.Y. Times, Mar. 31, 1996 (editorial) (stating that opponents of the ban argue that an exception to preserve the life of the mother is too narrow).

Ex. 665, ACOG, *The Partial-Birth Abortion Ban Act of 1995: Medical Assertions Made in the Debate on H.R. 1833* (undated) (list of quotations, with sources, from the house debate, expressing a variety of views on the ban).

Ex. 666, Memorandum from Bryant to ACOG Task Force on Third-Trimester Abortion of 9/26/96 (with attachments) (reviewing ACOG District II document *Medical Question and Answers on Third Trimester Termination Procedures*, expressing concern about possible lack of documentation for document's claims that "[the banned procedure] is done in hospitals by medical providers with special training," that "the medications which are used to anesthetize the mother cross the placenta and anesthetize the fetus," and that "this procedure is not done in the third trimester if the fetus is viable").

Ex. 667, Letter from Dr. Nusbaum to Dr. Murphy of 8/1/96 (suggesting specific wording changes to Information Sheet, and concluding that the assertion that "[t]his procedure is not done in the third trimester if the fetus is viable" is accurate in New York state) (attaching ACOG District II Information Sheet, *Medical Questions and Answers on Third Trimester Termination Procedures* & letter from Dr. Frigoletto to Dr. Murphy of 7/3/96) (suggesting severe interuterine sepsis as a third-trimester complication that might require termination of a pregnancy, questioning whether all intact D & Es are actually performed under general anesthesia, and questioning whether Information Sheet's assertion that "[t]his procedure is not done in the third trimester if the fetus is viable" is absolutely true).

Ex. 668, Memorandum from Elsa P. Brown to ACOG Task Force on Third-Trimester Abortion of 10/3/96 attaching National Abortion Federation Leaflet, *Later Abortions: Questions and Answers* (providing statistics on how often late abortions occur); Alan Guttmacher Institute, *Abortion Factbook 1992 Edition: Readings, Trends, and State and Local Data to 1988*

(Stanley K. Henshaw & Jennifer Van Vort eds. 1992) (same); Kenneth D. Kochanek, *Induced Terminations of Pregnancy: Reporting States, 1988*, 39 Monthly Vital Statistics Rep. 1, 6-7 (1991) (reporting statistics on frequency of abortion at various gestational ages for various demographic groups).

Ex. 671, Statement, ACOG, *Statement on H.R. 1833: The Partial-Birth Abortion Ban Act of 1995* (Nov. 1, 1995) (stating ACOG's opposition to ban and belief that congressional opinion should never be substituted for professional medical judgment).

Ex. 671, Letter from Dr. Hale (ACOG) to Sen. Dole of 11/6/95 (same).

Ex. 671, Letter from Dr. Hale (ACOG) to Pres. Clinton of 4/9/96 (same).

APPENDIX C

UNITED STATES PUBLIC LAWS
108th Congress - First Session
Convening January 7, 2003

PL 108-105 (S 3)
Nov. 5, 2003

PARTIAL-BIRTH ABORTION BAN ACT OF 2003

An Act To prohibit the procedure commonly known as partial-birth abortion.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Partial-Birth Abortion Ban Act of 2003".

SEC. 2. FINDINGS.

The Congress finds and declares the following:

(1) A moral, medical, and ethical consensus exists that the practice of performing a partial-birth abortion —an abortion in which a physician deliberately and intentionally vaginally delivers a living, unborn child's body until either the entire baby's head is outside the body of the mother, or any part of the baby's trunk past the navel is outside the body of the mother and only the head remains inside the womb, for the purpose of performing an overt act (usually the puncturing of the back of the child's skull and removing the baby's brains) that the person knows will kill the partially delivered infant, performs this act, and then completes delivery of the

dead infant—is a gruesome and inhumane procedure that is never medically necessary and should be prohibited.

(2) Rather than being an abortion procedure that is embraced by the medical community, particularly among physicians who routinely perform other abortion procedures, partial-birth abortion remains a disfavored procedure that is not only unnecessary to preserve the health of the mother, but in fact poses serious risks to the long-term health of women and in some circumstances, their lives. As a result, at least 27 States banned the procedure as did the United States Congress which voted to ban the procedure during the 104th, 105th, and 106th Congresses.

(3) In Stenberg v. Carhart, 530 U.S. 914, 932 (2000), the United States Supreme Court opined "that significant medical authority supports the proposition that in some circumstances, [partial birth abortion] would be the safest procedure" for pregnant women who wish to undergo an abortion. Thus, the Court struck down the State of Nebraska's ban on partial-birth abortion procedures, concluding that it placed an "undue burden" on women seeking abortions because it failed to include an exception for partial-birth abortions deemed necessary to preserve the "health" of the mother.

(4) In reaching this conclusion, the Court deferred to the Federal district court's factual findings that the partial-birth abortion procedure was statistically and medically as safe as, and in many circumstances safer than, alternative abortion procedures.

(5) However, substantial evidence presented at the Stenberg trial and overwhelming evidence presented and compiled at extensive congressional hearings, much

of which was compiled after the district court hearing in Stenberg, and thus not included in the Stenberg trial record, demonstrates that a partial-birth abortion is never necessary to preserve the health of a woman, poses significant health risks to a woman upon whom the procedure is performed and is outside the standard of medical care.

(6) Despite the dearth of evidence in the Stenberg trial court record supporting the district court's findings, the United States Court of Appeals for the Eighth Circuit and the Supreme Court refused to set aside the district court's factual findings because, under the applicable standard of appellate review, they were not "clearly erroneous". A finding of fact is clearly erroneous "when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed". Anderson v. City of Bessemer City, North Carolina, 470 U.S. 564, 573 (1985). Under this standard, "if the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently". Id. at 574.

(7) Thus, in Stenberg, the United States Supreme Court was required to accept the very questionable findings issued by the district court judge—the effect of which was to render null and void the reasoned factual findings and policy determinations of the United States Congress and at least 27 State legislatures.

(8) However, under well-settled Supreme Court jurisprudence, the United States Congress is not bound to accept the same factual findings that the Supreme

Court was bound to accept in Stenberg under the "clearly erroneous" standard. Rather, the United States Congress is entitled to reach its own factual findings—findings that the Supreme Court accords great deference—and to enact legislation based upon these findings so long as it seeks to pursue a legitimate interest that is within the scope of the Constitution, and draws reasonable inferences based upon substantial evidence.

(9) In Katzenbach v. Morgan, 384 U.S. 641 (1966), the Supreme Court articulated its highly deferential review of congressional factual findings when it addressed the constitutionality of section 4(e) of the Voting Rights Act of 1965. Regarding Congress' factual determination that section 4(e) would assist the Puerto Rican community in "gaining nondiscriminatory treatment in public services," the Court stated that "[i]t was for Congress, as the branch that made this judgment, to assess and weigh the various conflicting considerations * * *. It is not for us to review the congressional resolution of these factors. It is enough that we be able to perceive a basis upon which the Congress might resolve the conflict as it did. There plainly was such a basis to support section 4(e) in the application in question in this case.". Id. at 653.

(10) Katzenbach's highly deferential review of Congress' factual conclusions was relied upon by the United States District Court for the District of Columbia when it upheld the "bail-out" provisions of the Voting Rights Act of 1965 (42 U.S.C. 1973c), stating that "congressional fact finding, to which we are inclined to pay great deference, strengthens the inference that, in those jurisdictions covered by the Act, state actions discriminatory in effect are discriminatory in purpose". City of

Rome, Georgia v. U.S., 472 F. Supp. 221 (D.D.C. 1979) aff'd City of Rome, Georgia v. U.S., 446 U.S. 156 (1980).

(11) The Court continued its practice of deferring to congressional factual findings in reviewing the constitutionality of the must-carry provisions of the Cable Television Consumer Protection and Competition Act of 1992. See Turner Broadcasting System, Inc. v. Federal Communications Commission, 512 U.S. 622 (1994) (Turner I) and Turner Broadcasting System, Inc. v. Federal Communications Commission, 520 U.S. 180 (1997) (Turner II). At issue in the Turner cases was Congress' legislative finding that, absent mandatory carriage rules, the continued viability of local broadcast television would be "seriously jeopardized". The Turner I Court recognized that as an institution, "Congress is far better equipped than the judiciary to 'amass and evaluate the vast amounts of data' bearing upon an issue as complex and dynamic as that presented here", 512 U.S. at 665-66. Although the Court recognized that "the deference afforded to legislative findings does 'not foreclose our independent judgment of the facts bearing on an issue of constitutional law,'" its "obligation to exercise independent judgment when First Amendment rights are implicated is not a license to reweigh the evidence de novo, or to replace Congress' factual predictions with our own. Rather, it is to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence.". Id. at 666.

(12) Three years later in Turner II, the Court upheld the "must-carry" provisions based upon Congress' findings, stating the Court's "sole obligation is 'to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence.'"

520 U.S. at 195. Citing its ruling in Turner I, the Court reiterated that "[w]e owe Congress' findings deference in part because the institution 'is far better equipped than the judiciary to "amass and evaluate the vast amounts of data" bearing upon' legislative questions," id. at 195, and added that it "owe[d] Congress" findings an additional measure of deference out of respect for its authority to exercise the legislative power.". Id. at 196.

(13) There exists substantial record evidence upon which Congress has reached its conclusion that a ban on partial-birth abortion is not required to contain a "health" exception, because the facts indicate that a partial-birth abortion is never necessary to preserve the health of a woman, poses serious risks to a woman's health, and lies outside the standard of medical care. Congress was informed by extensive hearings held during the 104th, 105th, 107th, and 108th Congresses and passed a ban on partial-birth abortion in the 104th, 105th, and 106th Congresses. These findings reflect the very informed judgment of the Congress that a partial-birth abortion is never necessary to preserve the health of a woman, poses serious risks to a woman's health, and lies outside the standard of medical care, and should, therefore, be banned.

(14) Pursuant to the testimony received during extensive legislative hearings during the 104th, 105th, 107th, and 108th Congresses, Congress finds and declares that:

(A) Partial-birth abortion poses serious risks to the health of a woman undergoing the procedure. Those risks include, among other things: An increase in a woman's risk of suffering from cervical incompetence, a result of cervical dilation making it difficult or impossible for a woman to successfully carry a subsequent

pregnancy to term; an increased risk of uterine rupture, abruption, amniotic fluid embolus, and trauma to the uterus as a result of converting the child to a footling breech position, a procedure which, according to a leading obstetrics textbook, "there are very few, if any, indications for * * * other than for delivery of a second twin"; and a risk of lacerations and secondary hemorrhaging due to the doctor blindly forcing a sharp instrument into the base of the unborn child's skull while he or she is lodged in the birth canal, an act which could result in severe bleeding, brings with it the threat of shock, and could ultimately result in maternal death.

(B) There is no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures. No controlled studies of partial-birth abortions have been conducted nor have any comparative studies been conducted to demonstrate its safety and efficacy compared to other abortion methods. Furthermore, there have been no articles published in peer-reviewed journals that establish that partial-birth abortions are superior in any way to established abortion procedures. Indeed, unlike other more commonly used abortion procedures, there are currently no medical schools that provide instruction on abortions that include the instruction in partial-birth abortions in their curriculum.

(C) A prominent medical association has concluded that partial-birth abortion is "not an accepted medical practice", that it has "never been subject to even a minimal amount of the normal medical practice development," that "the relative advantages and disadvantages of the procedure in specific circumstances remain unknown," and that "there is no consensus among obstetricians about its use". The association has further

noted that partial-birth abortion is broadly disfavored by both medical experts and the public, is "ethically wrong," and "is never the only appropriate procedure".

(D) Neither the plaintiff in Stenberg v. Carhart, nor the experts who testified on his behalf, have identified a single circumstance during which a partial-birth abortion was necessary to preserve the health of a woman.

(E) The physician credited with developing the partial-birth abortion procedure has testified that he has never encountered a situation where a partial-birth abortion was medically necessary to achieve the desired outcome and, thus, is never medically necessary to preserve the health of a woman.

(F) A ban on the partial-birth abortion procedure will therefore advance the health interests of pregnant women seeking to terminate a pregnancy.

(G) In light of this overwhelming evidence, Congress and the States have a compelling interest in prohibiting partial-birth abortions. In addition to promoting maternal health, such a prohibition will draw a bright line that clearly distinguishes abortion and infanticide, that preserves the integrity of the medical profession, and promotes respect for human life.

(H) Based upon Roe v. Wade, 410 U.S. 113 (1973) and Planned Parenthood v. Casey, 505 U.S. 833 (1992), a governmental interest in protecting the life of a child during the delivery process arises by virtue of the fact that during a partial-birth abortion, labor is induced and the birth process has begun. This distinction was recognized in Roe when the Court noted, without comment, that the Texas parturition statute, which prohibited one from killing a child "in a state of being born and before actual birth," was not under attack. This inter-

est becomes compelling as the child emerges from the maternal body. A child that is completely born is a full, legal person entitled to constitutional protections afforded a "person" under the United States Constitution. Partial-birth abortions involve the killing of a child that is in the process, in fact mere inches away from, becoming a "person". Thus, the government has a heightened interest in protecting the life of the partially-born child.

(I) This, too, has not gone unnoticed in the medical community, where a prominent medical association has recognized that partial-birth abortions are "ethically different from other destructive abortion techniques because the fetus, normally twenty weeks or longer in gestation, is killed outside of the womb". According to this medical association, the "partial birth" gives the fetus an autonomy which separates it from the right of the woman to choose treatments for her own body".

(J) Partial-birth abortion also confuses the medical, legal, and ethical duties of physicians to preserve and promote life, as the physician acts directly against the physical life of a child, whom he or she had just delivered, all but the head, out of the womb, in order to end that life. Partial-birth abortion thus appropriates the terminology and techniques used by obstetricians in the delivery of living children—obstetricians who preserve and protect the life of the mother and the child—and instead uses those techniques to end the life of the partially-born child.

(K) Thus, by aborting a child in the manner that purposefully seeks to kill the child after he or she has begun the process of birth, partial-birth abortion undermines the public's perception of the appropriate role of a physician during the delivery process, and perverts a

process during which life is brought into the world, in order to destroy a partially-born child.

(L) The gruesome and inhumane nature of the partial-birth abortion procedure and its disturbing similarity to the killing of a newborn infant promotes a complete disregard for infant human life that can only be countered by a prohibition of the procedure.

(M) The vast majority of babies killed during partial-birth abortions are alive until the end of the procedure. It is a medical fact, however, that unborn infants at this stage can feel pain when subjected to painful stimuli and that their perception of this pain is even more intense than that of newborn infants and older children when subjected to the same stimuli. Thus, during a partial-birth abortion procedure, the child will fully experience the pain associated with piercing his or her skull and sucking out his or her brain.

(N) Implicitly approving such a brutal and inhumane procedure by choosing not to prohibit it will further coarsen society to the humanity of not only newborns, but all vulnerable and innocent human life, making it increasingly difficult to protect such life. Thus, Congress has a compelling interest in acting—indeed it must act—to prohibit this inhumane procedure.

(O) For these reasons, Congress finds that partial-birth abortion is never medically indicated to preserve the health of the mother; is in fact unrecognized as a valid abortion procedure by the mainstream medical community; poses additional health risks to the mother; blurs the line between abortion and infanticide in the killing of a partially-born child just inches from birth; and confuses the role of the physician in childbirth and should, therefore, be banned.

SEC. 3. PROHIBITION ON PARTIAL-BIRTH ABORTIONS.

(a) IN GENERAL.—Title 18, United States Code, is amended by inserting after chapter 73 the following:

"CHAPTER 74—PARTIAL-BIRTH ABORTIONS

"Sec.

"1531. Partial-birth abortions prohibited.

"§ 1531. Partial-birth abortions prohibited

"(a) Any physician who, in or affecting interstate or foreign commerce, knowingly performs a partial-birth abortion and thereby kills a human fetus shall be fined under this title or imprisoned not more than 2 years, or both. This subsection does not apply to a partial-birth abortion that is necessary to save the life of a mother whose life is endangered by a physical disorder, physical illness, or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself. This subsection takes effect 1 day after the enactment.

"(b) As used in this section—

"(1) the term 'partial-birth abortion' means an abortion in which the person performing the abortion—

"(A) deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and

"(B) performs the overt act, other than completion of delivery, that kills the partially delivered living fetus; and

"(2) the term 'physician' means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the doctor performs such activity, or any other individual legally authorized by the State to perform abortions: Provided, however, That any individual who is not a physician or not otherwise legally authorized by the State to perform abortions, but who nevertheless directly performs a partial-birth abortion, shall be subject to the provisions of this section.

"(c)(1) The father, if married to the mother at the time she receives a partial-birth abortion procedure, and if the mother has not attained the age of 18 years at the time of the abortion, the maternal grandparents of the fetus, may in a civil action obtain appropriate relief, unless the pregnancy resulted from the plaintiff's criminal conduct or the plaintiff consented to the abortion.

"(2) Such relief shall include—

"(A) money damages for all injuries, psychological and physical, occasioned by the violation of this section; and

"(B) statutory damages equal to three times the cost of the partial-birth abortion.

"(d)(1) A defendant accused of an offense under this section may seek a hearing before the State Medical Board on whether the physician's conduct was necessary to save the life of the mother whose life was endangered by a physical disorder, physical illness, or physical injury, including a life-endangering physical

condition caused by or arising from the pregnancy itself.

"(2) The findings on that issue are admissible on that issue at the trial of the defendant. Upon a motion of the defendant, the court shall delay the beginning of the trial for not more than 30 days to permit such a hearing to take place.

"(e) A woman upon whom a partial-birth abortion is performed may not be prosecuted under this section, for a conspiracy to violate this section, or for an offense under section 2, 3, or 4 of this title based on a violation of this section.".

(b) CLERICAL AMENDMENT.—The table of chapters for part I of title 18, United States Code, is amended by inserting after the item relating to chapter 73 the following new item:

"74. Partial-birth abortions.....1531".

Approved November 5, 2003.